

# **EXHIBIT A**

Assigned for all purposes to: Spring Street Courthouse, Judicial Officer: Carolyn Kuhl

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**SUPERIOR COURT OF THE STATE OF CALIFORNIA  
 FOR THE COUNTY OF LOS ANGELES**

STACIA CULLORS, an individual; LAYLA  
 CULLORS, NOELANI CULLORS and  
 VIVIENNE CULLORS, through their  
 guardian ad litem STACIA CULLORS;  
 ANTHONY BACANI, an individual;  
 DAHLIA BACANI and ELIAS BACANI,  
 through their guardian ad litem ANTHONY  
 BACANI; JENNIFER CULLORS, an  
 individual; AVA CULLORS and JOSHUA  
 CULLORS, through their guardian ad litem  
 JENNIFER CULLORS, and on behalf of all  
 others similarly situated,

Plaintiffs,

vs.

BEECH-NUT NUTRITION COMPANY;  
 NURTURE, INC.; PLUM, INC. d.b.a.  
 PLUM ORGANICS; GERBER PRODUCTS  
 COMPANY; WALMART, INC.; SPROUT  
 FOODS, INC.; and DOES 1 through 20  
 inclusive,

Defendants.

Case No.: **22STCV07017**

**COMPLAINT FOR DAMAGES**

**(1) STRICT PRODUCTS LIABILITY –  
 FAILURE TO WARN**

**(2) NEGLIGENCE – FAILURE TO  
 WARN**

**(3) NEGLIGENT PRODUCT DESIGN**

**(4) NEGLIGENT MANUFACTURING**

**(5) NEGLIGENT  
 MISREPRESENTATION**

**(6) VIOLATIONS OF THE BUSINESS &  
 PROFESSIONS CODE SECTIONS 17200  
 ET SEQ. (“UCL”)**

**(7) VIOLATION OF CALIFORNIA  
 CONSUMER LEGAL REMEDIES ACT,  
 CAL. CIV. CODE SECTION 1770, et seq.  
 (“CLRA”)**

**(8) QUASI-CONTRACT/UNJUST  
 ENRICHMENT**

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COME NOW Plaintiffs STACIA CULLORS, an individual, LAYLA CULLORS, NOELANI CULLORS and VIVIENNE CULLORS, through their guardian ad litem STACIA CULLORS, ANTHONY BACANI, an individual, DAHLIA BACANI and ELIAS BACANI, through their guardian ad litem ANTHONY BACANI, JENNIFER CULLORS, an individual, as well as AVA CULLORS and JOSHUA CULLORS, through their guardian ad litem JENNIFER CULLORS, and on behalf of all others similarly situated (collectively “Plaintiffs”), and through their counsel of record, Beverly Hills Trial Attorneys, P.C., file this class action complaint against BEECH-NUT NUTRITION COMPANY (“BEECH-NUT”), NURTURE, INC. (“NURTURE”), PLUM, INC. d.b.a. PLUM ORGANICS (“PLUM”), GERBER PRODUCTS COMPANY (“GERBER”), WALMART, INC. (“WALMART”), SPROUT FOODS, INC. (“SPROUT”), and DOES 1 through 20, inclusive (collectively “Defendants”), seeking damages and relief on behalf of themselves and for all others similarly situated for: Strict products liability (failure to warn), negligence (failure to warn), negligent product design, negligent manufacturing, negligent misrepresentation, violation of California’s Unfair Competition Law - *Business & Professions Code* sections 17200, *et seq.* (“UCL”), California’s Consumer Legal Remedies Act - *Civil Code* sections 1750, *et seq.* (“CLRA”), unjust enrichment, and related claims as stated herein as below. Unless explicitly stated to the contrary, all allegations are based upon information and belief.

### **INTRODUCTION**

This case involves a series of manufacturers, BEECH-NUT NUTRITION COMPANY (“Beech-Nut”), NURTURE, INC. (“Nurture”), PLUM, INC. d.b.a. PLUM ORGANICS (“Plum”), GERBER PRODUCTS COMPANY (“Gerber”), WALMART, INC. (“Walmart”), and SPROUT FOODS, INC. (“Sprout”) (collectively referred to as “Defendants”) that knowingly sold baby food products (“Baby Foods”) which contain high levels of toxic heavy metals including mercury, lead, arsenic and cadmium to Plaintiffs.

Plaintiffs are consumers who purchased Defendants’ Baby Foods reasonably believing that such baby foods are safe, nutritious, and free from harmful toxins contaminants and chemicals.

1 In reality, and despite Defendants' promises and reassurances to parents that their  
 2 products are pure, natural, safe and healthy, these Baby Foods contain heavy metals that are not  
 3 pure, are unnatural, are unsafe, and pose a major risk to babies and infants. Had parents and/or  
 4 guardians been fully informed about the contents of the Baby Foods they purchased, they would  
 5 not have bought these Baby Foods nor fed them to their children.

6 In February 2021, the U.S. House of Representatives' Subcommittee on Economic and  
 7 Consumer Policy, Committee on Oversight and Reform released a report ("Report") containing  
 8 outrageous details of Defendants' tainted Baby Foods based on the submission of internal test  
 9 results and company documents. Through this report, it came to light that Defendants' Baby  
 10 Foods are laced with shocking amounts of toxic heavy metals. Specifically, the Subcommittee  
 11 found that Defendants sell Baby Foods containing as much as 180 parts per billion ("ppb")<sup>1</sup>  
 12 inorganic arsenic, 6441 ppb lead, 10 ppb mercury, and manufacture their Baby Foods using  
 13 ingredients containing as much as 913.4 ppb arsenic, 886.9 ppb lead, and 344.55 ppb cadmium,  
 14 far beyond the regulatory standards.

15 These numbers are outrageous given that in comparison, the U.S. Food and Drug  
 16 Administration ("FDA") has set the maximum allowable levels in bottled water at 10 ppb  
 17 inorganic arsenic, 5 ppb lead and 5 ppb cadmium, and the U.S. Environmental Protection  
 18 Agency ("EPA") has capped the allowable level of mercury in drinking water at 2 ppb. The  
 19 Report held that the test results of Baby Foods and their ingredients "eclipse those levels:  
 20 including results up to **91 times** the arsenic level, up to **177 times** the lead level, up to **69 times**  
 21 the cadmium level, and up to **5 times** the mercury level."<sup>2</sup>

22 The House Staff Report highlighted the high levels of high toxic metals in numerous  
 23 baby foods produced by Defendants, namely Defendants Beech-Nut, Nurture and Gerber who  
 24  
 25

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26  
 27 <sup>1</sup> Ppb (or ppbm) is used to measure the concentration of a contaminant in soils, sediments, and water. 1  
 ppb equals 1 microgram of substance per kg of solid.

28 <sup>2</sup> Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform  
 U.S. House of Representatives, *Baby Foods are Tainted with Dangerous Levels of Arsenic, Lead,  
 Cadmium and Mercury* (Feb. 4, 2021) ("Subcommittee Report") at 4 (attached as Exhibit "A").

1 cooperated with Congress's investigation. Defendants Plum, Walmart and Sprout refused  
 2 cooperation with the Subcommittee which was highly suggestive of their misconduct given  
 3 their choice not to cooperate with federal regulators.<sup>3</sup>

4 Furthermore, in the Report, the Subcommittee concluded that "[m]anufacturers  
 5 knowingly sell these products to unsuspecting parents, in spite of internal company standards  
 6 and test results, and without any warning labeling whatsoever."<sup>4</sup> Additionally, the Report held  
 7 that exposure to toxic heavy metals causes:

- 8 a) permanent decreases in IQ
- 9 b) diminished future economic productivity
- 10 c) increased risk of future criminal and antisocial behavior in children.
- 11 d) affected and endanger infant neurological development and long-term brain
- 12 function.
- 13 e) and other unknown and harmful effects to children.<sup>5</sup>

14 Defendants knew or should have known that their Baby Foods contain significant levels  
 15 of toxic heavy metals, including arsenic, lead, cadmium, and mercury. Defendants knew or  
 16 should have known that such toxic metals are not fit for consumption, and knew or should have  
 17 known that its Baby Foods are detrimental to the health of babies. In fact, Defendants had no  
 18 reasonable ground for believing that their Baby Foods were free from toxic heavy metals, or  
 19 that such toxic metals were appropriate for sale in Baby Foods.

20 The high levels of toxic heavy metals found in Defendants' Baby Foods are as a result of  
 21 the ingredients used by Defendants to manufacture these Baby Foods, disregard of regulatory  
 22 standards, and corporate policies which failed to test finished products before they were  
 23 distributed into the market, and the setting of dangerously inflated internal limits which  
 24

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25  
26  
27  
28 <sup>3</sup> *Id.* at 2.

<sup>4</sup> *Id.* at 59.

<sup>5</sup> *Id.* at 2.

1 Defendants easily ignored, leading to the purchase of parents and/or guardians of these products  
2 and eventually consumption by vulnerable children.

3 Defendants continue to wrongfully induce consumers to purchase its Baby Foods that are  
4 not as advertised. Plaintiffs are unable to purchase Baby Foods from any of the Defendants with  
5 any degree of certainty that these foods will not contain toxic heavy metals or other  
6 undesirable toxins or contaminants.

7 Plaintiffs brings this proposed consumer class action individually and on behalf of all other  
8 members of the Class, who, from the applicable limitations period up to and including the  
9 present, purchased for use any of Defendants' tainted Baby Foods.

10 As a result of Defendants' negligent, reckless, and/or knowingly deceptive conduct as  
11 alleged herein, Plaintiffs were injured when they paid the purchase price or a price premium  
12 for baby foods that did not deliver what they promised. They paid the purchase price on the  
13 assumption that the labeling of the baby foods was accurate and that it was free of toxic heavy  
14 metals and safe to ingest. Plaintiffs would not have paid this money or fed their children food  
15 containing toxic heavy metals had they known the truth that Defendants' products contain  
16 excessive degrees of toxic heavy metals.

## 17 **PARTIES**

### 18 **PLAINTIFFS**

19 1. Plaintiffs are, and at all times relevant here, have been citizens of the state of  
20 California. Additionally, unnamed Class Plaintiffs, are, and at all times relevant herein, were  
21 residents of the State of California.

22 2. In making their purchasing decisions, Plaintiffs Stacia Cullors, Anthony Bacani  
23 and Jennifer Cullors consider how healthy baby food products are, including the ingredients and  
24 nutritional value of those products. In fact, these baby foods by the various Defendants' brands,  
25 which were more expensive than cheaper alternatives, were purchased because Plaintiffs Stacia  
26 Cullors, Anthony Bacani and Jennifer Cullors were led to believe that the Baby Foods from these  
27 brands were healthier and safer for consumption by the remaining Plaintiffs.  
28

3. On numerous occasions, Plaintiffs Stacia Cullors, Anthony Bacani and Jennifer Cullors have purchased the Baby Foods from various stores including Target, Walmart, Albertsons and Walgreens. Specifically, Plaintiff Stacia Cullors purchased hundreds of different varieties of Defendants' baby food products in California from September 2009 to May 2012, and again from February 2020 to December 2021; Plaintiff Anthony Bacani purchased hundreds of different varieties of Defendants' baby food products in California from March 2011 to November 2014 and again from May 2016 to January 2019; and Plaintiff Jennifer Cullors purchased hundreds of different varieties of Defendants' baby food products in California from January 2011 to September 2013, and again from February 2020 to December 2021.

4. Plaintiffs LAYLA CULLORS, NOELANI CULLORS, VIVIENNE CULLORS, DAHLIA BACANI, ELIAS BACANI, AVA CULLORS and JOSHUA CULLORS, were exposed to and consumed the below-mentioned Baby Foods over hundreds of times during a span of several years. Specifically, Plaintiff Layla Cullors was exposed to and consumed these Baby Foods over 100 times between September 2009 to May 2012; Plaintiff Noelani Cullors was exposed to and consumed these Baby Foods over 100 times between February 2020 to December 2021; Plaintiff Vivienne Cullors was exposed to and consumed these Baby Foods over 50 times between September 2021 to December 2021; Plaintiff Dahlia Bacani was exposed to and consumed these Baby Foods over 100 times between March 2011 to November 2014; Plaintiff Elias Bacani was exposed to and consumed these Baby Foods over 100 times between May 2016 to January 2019; Plaintiff Ava Cullors was exposed to and consumed these Baby Foods over 100 times between January 2011 to September 2013; and Plaintiff Joshua Cullors was exposed to and consumed these Baby Foods over 100 times between February 2020 to December 2021.

5. The Baby Foods purchased and consumed by Plaintiffs from Beech-Nut during the above-mentioned time periods were the following:

- Beech-Nut Rice Cereal (recalled on June 8, 2021)
- Rice Single Grain Baby Cereal
- Oatmeal Whole Grain Baby Cereal
- Classics Sweet Carrots – Stage 2



- Organics Just Carrots – Stage 1
- Naturals Just Sweet Potatoes – Stage 1
- Classics Sweet Potatoes – Stage 2
- Classics Sweet Peas – Stage 2
- Beechnut Naturals just Butternut Squash – Stage 1
- Organic Just Apples
- Naturals Bananas – Stage 1
- Naturals Beets, Pear & Pomegranate
- Classics mixed vegetables – Stage 2
- Classics Chicken & Chicken Broth
- Classics Turkey and Turkey Broth
- Breakfast on the go Yogurt, Banana and Mixed Berry Blend

6. The Baby Foods purchased and consumed by Plaintiffs from Nurture, which sells Baby Foods under the brand name HappyBABY, during the above-mentioned time periods were the following:

- Oats & Quinoa Baby Cereal Organic Whole Grains with Iron – Sitting Baby
- Oatmeal Baby Cereal, clearly crafted – Organic Whole Grains for Sitting baby
- Sweet Potatoes – Stage 1
- Organic Pears – Stage 1
- Clearly Crafted Prunes Organic Baby Food
- Simple Combos Apples, Spinach & Kale
- Superfood Puffs – Apple & Broccoli Organic Grain Snack
- Superfood Puffs Organic Grain Snack – Sweet Potato & Carrot
- Organic Teethers Blueberry & Purple Carrot – Sitting
- Apples, Sweet Potatoes & Granola Clearly Crafted Organic Baby food
- Organic Rice Cakes Puffed Rice Snack

7. The Baby Foods purchased and consumed by Plaintiffs from Plum, during the above-mentioned time periods were the following:

- Just Sweet Potato Organic Baby Food – 1, 4 months and up
- Just Peaches – organic baby food – for 4+ months (stage 1)
- Just Prunes Organic Baby Food – 1, 4 months & up
- Little Teethers Organic Multigrain Teething Wafers – Banana with Pumpkin – Baby Crawler

8. The Baby Foods purchased and consumed by Plaintiffs from Gerber, during the above-mentioned time periods were the following:

- Banana – Sitter 2<sup>nd</sup> Foods
- Peach – Sitter 2<sup>nd</sup> Foods
- Pear – Sitter 2<sup>nd</sup> Foods
- Organic Mango Apple Carrot Kale – Sitter 2<sup>nd</sup> food
- Carrot Pear Blackberry – Sitter 2<sup>nd</sup> Foods
- Organic Apple Blueberry Spinach – Sitter 2<sup>nd</sup> Food
- Apple Sweet Potato with Cinnamon – Toddler 12+ months
- Carrot Sweet Potato Pea – Sitter 2<sup>nd</sup> Foods
- Apple Juice from Concentrate – Toddler 12+ months
- Apple Prune Juice from Concentrate – Toddler 12+ months
- Variety Pack Juices from Concentrate – White Grape
- Pear Juice from Concentrate 100% Juice – Toddler 12+ months
- Mashed Potatoes & Gravy with Roasted Chicken and a side of carrots – toddler
- Chicken Rice dinner – Sitter 2<sup>nd</sup> Foods
- Turkey Rice Dinner – Sitter 2<sup>nd</sup> Foods
- Beef and Gravy 2<sup>nd</sup> foods
- Ham and Gravy 2<sup>nd</sup> foods
- Puffs Banana Cereal Snack – Crawler 8+ months
- Teether Wheels – Apple Harvest – Crawlers
- Yogurt Blends Strawberry Snack – Crawler 8+ months
- Arrowroot Biscuits – crawler 10+ months
- Rice Single Grain Cereal
- Multigrain Cereal – Sitter 2<sup>nd</sup> Foods
- Oatmeal Single Grain Cereal
- Carrot – Sitter 2<sup>nd</sup> food
- Carrot – Supported Sitter 1<sup>st</sup> Foods
- Sweet Potato Supported Sitter 1<sup>st</sup> Foods Tub
- Sweet Potato – Sitter 2<sup>nd</sup> food
- Sweet Potato – Supported Sitter 1<sup>st</sup> Foods
- Pea – Sitter 2<sup>nd</sup> Foods
- Green Bean – Sitter 2<sup>nd</sup> Food

9. The Baby Foods purchased and consumed by Plaintiffs from Walmart, under the brand name Parent's Choice, during the above-mentioned time periods were the following:

- Parent's Choice Stage 2 (6+ months) Carrot
- Parent's Choice Stage 1 (4-6 months) Sweet Potato
- Parent's Choice Stage 2 (6+ months) Organic Butternut Squash Vegetable Puree
- Parent's Choice Stage 3 (9+ months) Little Hearts Strawberry Yogurt Cereal
- Parent's Choice Rice Baby Cereal (recalled in October 2021)

10. The Baby Foods purchased and consumed by Plaintiffs from Sprout during

1 the above-mentioned time periods were the following:

- 2 • Prunes Organic Baby Food
- 3 • Carrot Apple Mango Organic Baby Food
- 4 • Butternut Chickpea Quinoa & Dates Organic Baby Food
- 5 • Organic Quinoa Puffs Baby Cereal Snack – Apple & Kale

6 11. All of these products were purchased and consumed by Plaintiffs because they  
7 believed these products were healthy Baby Foods based on the labeling on the products and the  
8 advertisements by Defendants which promoted these Baby Foods as organic and nutritious. At  
9 no time during their purchase and consumption were Plaintiffs aware that Defendants' claims  
10 with regards to the Baby Foods were false and misleading, and that these products actually  
11 contained high levels of heavy metals, chemicals or toxins.

12 12. Plaintiffs would not have purchased these Baby Foods, at times paying premium  
13 prices, nor would have consumed these products if they were aware of the presence of the alleged  
14 heavy metals, chemicals, and toxins.

#### 15 **DEFENDANTS**

16 13. Defendant Beech-Nut Nutrition Company ("Beech-Nut") is a citizen of  
17 Delaware and New York with its principal place of business located at 1 Nutritious Pl.,  
18 Amsterdam, NY 12010. Beech-Nut sells Baby Foods under the brand name Beech-Nut. Beech-  
19 Nut produces Baby Foods aimed at infants 4+ months up to 12+ months and includes a variety of  
20 cereals, "jars", and "pouches" for these age groups. At all relevant times, Beech-Nut has  
21 conducted business and derived substantial revenue from its manufacturing, advertising,  
22 distributing, selling, and marketing of Baby Foods within the State of California and Los Angeles  
23 County.

24 14. Defendant Nurture, Inc. ("Nurture"), is a citizen of Delaware and New York  
25 with its principal place of business located at 40 Fulton St, 17th Floor, New York, NY 10038-  
26 1850. Nurture owns Happy Family Brands (including Happy Family Organics) and sells Baby  
27 Foods under the brand name HappyBABY. Nurture classifies its HappyBABY range of products  
28 according to three categories: "baby", "tot", and "mama". The "baby" category is comprised of

1 foods, including “starting solids”, intended for age groups 0-7+ months, the “tot” category covers  
 2 12+ months, and “mama” includes infant formulas for newborn babies. At all relevant times,  
 3 Nurture has conducted business and derived substantial revenue from its manufacturing,  
 4 advertising, distributing, selling, and marketing of HappyBABY within the State of California  
 5 and Los Angeles County. At all times material hereto, Defendants, and each of them, engaged in  
 6 their unfair and deceptive billing practices within the jurisdiction of this Court.

7 15. Defendant PLUM, INC. d.b.a. PLUM ORGANICS is a citizen of Delaware  
 8 and California with its principal place of business located at 1485 Park Avenue, Emeryville,  
 9 California 94608. Plum sells Baby Foods under the brand name Plum Organics. Plum's products  
 10 are divided into groups according to the targeted infant or toddler age and/or type of food product.  
 11 For example, there are five groups designated for the youngest infants: Stage 1 (4+ months old),  
 12 Stage 2 (6+ months old), Stage 3 (6+ months old), “Super Puffs”, and “Little Teethers”. At all  
 13 relevant times, Plum has conducted business and derived substantial revenue from its  
 14 manufacturing, advertising, distributing, selling, and marketing of Baby Foods within the State  
 15 of California and Los Angeles County.  
 16

17 16. Defendant Gerber Products Company (“Gerber”) is a citizen of Michigan  
 18 with its principal place of business located at 445 State Street, Fremont, MI 49413-0001. Gerber  
 19 sells Baby Foods under the brand name Gerber. Gerber organizes its products into broad  
 20 categories of “formula”, “baby cereal”, “baby food”, “snacks”, “meals & sides” “beverages” and  
 21 “organic”. At all relevant times, Gerber has conducted business and derived substantial revenue  
 22 from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within the  
 23 State of California and Los Angeles County.

24 17. Defendant Walmart, Inc. (“Walmart”) is a citizen of Delaware and Arkansas  
 25 with its principal place of business located at 702 S.W. 8th St. Bentonville, AK 72716. Walmart  
 26 sells Baby Foods under the brand name Parent's Choice. Walmart's Parent's Choice offers a wide  
 27 selection of baby foods ranging from “sweet potatoes & corn” to “toddler cookies” and “yogurt  
 28 bites”. At all relevant times, Walmart has conducted business and derived substantial revenue

1 from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within the  
2 State of California and Los Angeles County.

3 18. Defendant Sprout Foods, Inc. (“Sprout”) is a citizen of Delaware and New  
4 Jersey with its principal place of business located at 50 Chestnut Ridge Rd, Montvale, NJ 07645.  
5 Sprout sells Baby Foods under the brand name Sprout Organic Foods. Sprout organizes its Baby  
6 Foods selection according to three categories: Stage 2 (6 months+); Stage 3 (8 months+); and  
7 Toddler. At all relevant times, Sprout has conducted business and derived substantial revenue  
8 from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods within the  
9 State of California and Los Angeles County.

10 19. Plaintiffs are uncertain of the true names and capacities of the Defendants  
11 sued herein as DOES 1 through 20, inclusive, and therefore, sue said Defendants under said  
12 fictitious names. Plaintiffs will amend this complaint further to insert the true names and  
13 capacities of said Defendants when the same are discovered. Plaintiffs are informed and believe  
14 and thereon allege that each of the fictitiously named Defendants are responsible in some manner  
15 for the occurrences herein alleged and are liable to the named Plaintiffs, and all other similarly  
16 situated on the claims hereinafter set forth. Said named Defendants and fictitiously named  
17 Defendants are hereinafter collectively referred to as “Defendants.”

18 20. At all times mentioned, all Defendants and each of them, inclusive, were  
19 engaged in the business of researching, developing, designing, licensing, manufacturing,  
20 distributing, selling, marketing, and/or introducing into interstate commerce and into the State of  
21 California, including in Los Angeles County, either directly or indirectly through third parties or  
22 related entities, Baby Foods.

23 21. At relevant times, Defendants and each of them, inclusive, conducted regular  
24 and sustained business and engaged in substantial commerce and business activity in the State of  
25 California, which included but was not limited to selling, marketing and distributing Baby Foods  
26 in the State of California and Los Angeles County.

27 22. At all relevant times, Defendants and each of them, inclusive, expected or  
28

1 should have expected that their acts would have consequences within the United States of  
 2 America including the State of California and including Los Angeles County, said Defendants  
 3 derived and derive substantial revenue therefrom.

#### 4 **JURISDICTION AND VENUE**

5 23. This Court has jurisdiction over this action pursuant to the California Constitution.

6 24. The Court has personal jurisdiction over Defendant Plum because this Defendant is  
 7 a citizen of the State of California. Additionally, the Court has personal jurisdiction over Beech-  
 8 Nut, Nurture, Gerber, Walmart, Sprout and Plum as each of these Defendants is authorized and  
 9 licensed to conduct business in the State of California, maintains and carries on systematic and  
 10 continuous contacts in the State of California, and conducts business within the State of  
 11 California, and/or otherwise intentionally avails itself of the California market through its  
 12 promotion, sales, distribution and marketing within the State to render the exercise of jurisdiction  
 13 by this Court permissible.

14 25. Venue is proper in this Court because all Defendants do business in Los Angeles  
 15 County, and substantial parts of the events giving rise to Plaintiffs' claims occurred in this judicial  
 16 district.

#### 17 **GENERAL ALLEGATIONS**

18 26. Inorganic arsenic, lead, cadmium, and mercury are toxic heavy metals (the  
 19 "Toxic Heavy Metals"). The United States Food and Drug Administration ("FDA") and the  
 20 World Health Organization ("WHO") have declared these Toxic Heavy Metals dangerous to  
 21 human health. Specifically, FDA states that these Toxic Heavy Metals have "no established  
 22 health benefit," "lead to illness, impairment, and in high doses, death," and because of  
 23 bioaccumulation, "even low levels of harmful metals from individual food sources, can  
 24 sometimes add up to a level of concern."<sup>6</sup>

25 27. The dangerous effects of these toxins are worsened in developing and  
 26 vulnerable bodies and brains of babies and children, who FDA explains are at the greatest risk of

27  
 28 <sup>6</sup> FDA, *Metals and Your Food*, available at: <https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food>.

1 harm. *See* Subcommittee Report, p. 2. Exposure, such as ingestion, of Toxic Heavy Metals by  
 2 babies and children leads to untreatable and permanent brain damage, resulting in reduced  
 3 intelligence and behavioral problems. For instance, scientific studies have connected  
 4 exposure to lead to a substantial decrease in children’s total IQ points and their lifetime earning  
 5 capacity. *See* Subcommittee Report, p. 9.

6 28. Additionally, Exposure to Toxic Heavy Metals (such as arsenic, lead, cadmium,  
 7 and mercury) causes permanent decreases in IQ, diminished future economic productivity, and  
 8 increased risk of future criminal and antisocial behavior in children, and can endanger infant  
 9 neurological development and long-term brain function. *See*, Subcommittee Report, p. 2.

10 29. Because Toxic Heavy Metals have no benefits and severe detriments, Healthy  
 11 Babies Bright Futures (“HBBF”), an alliance of nonprofit organizations, scientists, and donors  
 12 whose work is cited favorably in the Subcommittee Report, has concluded that baby food  
 13 should have no measurable amount of arsenic, lead, cadmium, or mercury. In fact, in October  
 14 2019, HBBF published a report investigating the presence of Toxic Heavy Metals in baby foods.<sup>7</sup>  
 15 The HBBF Report found that 95% of “baby foods tested were contaminated with one or more of  
 16 four toxic heavy metals – arsenic, lead, cadmium and mercury. All but nine of 168 baby foods  
 17 tested, contained at least one metal, though most contained more than one.<sup>8</sup> Specifically, the  
 18 HBBF report identified “puffs and other snacks made with rice flour,” “teething biscuits and rice  
 19 rusks,” “infant rice cereal,” “apple, pear, grape, and other fruit juices,” and carrots and sweet  
 20 potatoes” manufactured by the Defendants as particularly high in Toxic Heavy Metals.<sup>9</sup> Given  
 21 these results, and in response to reports alleging high levels of Toxic Heavy Metals in baby  
 22 food sold in the United States, the House Subcommittee launched an investigation into the  
 23 presence of Toxic Heavy Metals in certain brands of baby food, including Defendants’ baby  
 24 food, and the results of the investigation were set forth in the Subcommittee Report, which was  
 25 released on February 4, 2021. Defendants Walmart, Plum, and Sprout refused to cooperate with  
 26 the Subcommittee’s investigation.

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26 <sup>7</sup> Healthy Babies Bright Futures, What’s in My Baby’s Food? A National Investigation Finds 95 Percent  
 27 of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic and Lead (Oct.  
 28 2019) (“HBBF Report”) (attached as Exhibit “B”).

<sup>8</sup> *Id.* at 6.

<sup>9</sup> *Id.* at 10-11.



***Arsenic in Defendant's Baby Food***

30. According to the Subcommittee Report, arsenic was present in all brands of Baby food responding to the House Subcommittee's investigation. In particular, Defendant Nurture (HappyBABY) sold baby foods after tests showed they contained as much as 180 parts per billion (ppb) inorganic arsenic. Over 25% of the products Nurture tested before sale contained over 100 ppb inorganic arsenic. Nurture's testing shows that the typical baby food product it sold contained 60 ppb inorganic arsenic. Furthermore, Defendant Beech-Nut used ingredients that test results showed have as high as 913.4 ppb arsenic. In fact, Beech-Nut routinely used high-arsenic additives that tested over 300 ppb arsenic to address product characteristics such as "crumb softness." On June 8, 2021, four months following the Congressional findings, Beech-Nut issued a voluntary recall of its infant single grain rice cereal and exited the rice cereal market completely, confirming that its products exceed regulatory arsenic limits. Additionally, Defendant Gerber used high-arsenic ingredients, using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic.

31. The levels of toxic arsenic in Defendant's baby food far exceeded the 10 ppb Limit the FDA has set for arsenic in bottled water that is legal to sell to any consumer, even full-grown adults.<sup>10</sup>

32. Arsenic is the most dangerous of the Toxic Heavy Metals at issue and poses the most significant risk to human health.<sup>11</sup> Currently known risks of arsenic to health include, but are not limited to, respiratory, gastrointestinal, neurological and immunological effects, as well as damaging effects on the central nervous system and cognitive development in children.<sup>12</sup>

***Lead in Defendant's Baby Food***

33. Lead was also present in Defendants' baby food. Specifically, the Subcommittee Report found that Defendant Nurture (HappyBABY) sold finished baby food products that tested as high as 641 ppb lead, and that almost 20% of the baby food products that Nurture tested contained over 10 ppb lead. Furthermore, the report found that Defendant Beech-Nut used ingredients containing as much as 886.9 ppb lead, and that Defendant Beech-Nut used many

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<sup>10</sup> Subcommittee Report at p. 4.

<sup>11</sup> *Id.* at 10.

<sup>12</sup> Agency for Toxic Substances and Disease Registry, ATSDR's Substance Prior List (2019), available at <http://www.atsdr.cdc.gov/spl/index.html#2019spl>.



1 ingredients with high lead content, including 483 that contained over 5 ppb lead, 89 that contained  
 2 over 15 ppb lead, and 57 that contained over 20 ppb lead. Additionally, Defendant Gerber used  
 3 ingredients that tested as high as 48 ppb lead, and used many ingredients containing over 20 ppb  
 4 lead.

5 34. For comparison, the FDA has set the maximum level of lead in bottled water at  
 6 5 ppb.<sup>13</sup>

7 35. Lead is the second most dangerous of the Toxic Heavy Metals discussed in  
 8 the Subcommittee Report because lead can accumulate in the body, and even small doses of  
 9 lead have deleterious effects on children, including health, behavioral, cognitive, and  
 10 development issues. The FDA states that “[h]igh levels of lead exposure can seriously harm  
 11 children’s health and development, specifically the brain and nervous system.”<sup>14</sup>

### 12 *Cadmium in Defendant’s Baby Food*

13 36. Cadmium was another Toxic Heavy Metal found to be present in all brands of  
 14 baby food subject to the House Subcommittee’s investigation.<sup>15</sup> In particular, Defendant  
 15 Beech-Nut used 105 ingredients that tested over 20 ppb cadmium, with some testing much  
 16 higher, up to 344.55 ppb cadmium. Sixty-five percent of Defendant Nurture’s (HappyBABY)  
 17 finished baby food products contained more than 5 ppb cadmium, while seventy-five percent of  
 18 Gerber’s carrots contained cadmium in excess of 5 ppb, with some containing up to 87 ppb  
 19 cadmium.

20 37. For comparison, the FDA has set the maximum level of cadmium in bottled  
 21 water at 5 ppb.<sup>16</sup>

22 38. Cadmium is the seventh most dangerous heavy metal toxin according to the  
 23 ATSDR. Exposure to cadmium is linked with decreases in IQ and development of Attention  
 24 Deficit Hyperactive Disorder (“ADHD”). The EPA and FDA set the limit at 5 ppb of cadmium  
 25 in drinking water and bottled water. The WHO limits cadmium in drinking water at 3 ppb.

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26 <sup>13</sup> Subcommittee Report at p. 4.

27 <sup>14</sup> FDA, *Metals and Your Food*, available at: [https://www.fda.gov/food/chemicals-metals-pesticides-](https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food)  
 28 [food/metals-and-your-food](https://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food).

<sup>15</sup> Subcommittee Report at p. 3.

<sup>16</sup> *Id.* at 4.

***Mercury in Defendant's Baby Food***

39. Lastly, Mercury another Toxic Heavy Metal was found to be present in all brands of baby food subject to the House Subcommittee's investigation. *See*, Subcommittee Report, p. 4. The report found that Defendant Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury, Defendant Beech-Nut does not even test for mercury in baby food, and Defendant Gerber rarely tests for mercury in its baby foods.

40. These numbers are outrageous given that in comparison, the U.S. Food and Drug Administration ("FDA") has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic, 5 ppb lead and 5 ppb cadmium, and the U.S. Environmental Protection Agency ("EPA") has capped the allowable level of mercury in drinking water at 2 ppb. It is of importance to note that these limits were created in reference to **adult** exposure, not infants, who are much more vulnerable and susceptible to various illnesses.

***Independent Data with Regards to Defendants Walmart, Plum and Sprout***

41. Walmart, Plum, and Sprout refused to cooperate with the Subcommittee's investigation, highly indicative of their wrongdoing, but nonetheless independent data confirms that the baby food of these companies is similarly tainted, as the HBBF report observed that Walmart's Parent's Choice brand products contain 66 ppb inorganic arsenic, 26.9 ppb lead, 26.9 ppb cadmium, and 2.05 ppb mercury.<sup>17</sup>

42. Plum refused to produce its testing standards and specific testing results to the Subcommittee.<sup>18</sup> In fact, it has hidden its policies and the actual level of toxic heavy metals in its products and instead, provided the Subcommittee with a spreadsheet declaring that every one of its products "meets criteria," while declining to state what those criteria are.<sup>19</sup> It is troubling that Plum admitted that for mercury, the company has *no* criterion whatsoever, stating: "No

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<sup>17</sup> *See* HBBF Report at 21, 22, 25-27.

<sup>18</sup> Subcommittee Report at p. 44.

<sup>19</sup> Campbell, Product Heavy Metal Test Results (Dec. 11, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf>).

specific threshold established because no high-risk ingredients are used.” Nonetheless, Plum still marketed every food as “meets criteria” for mercury, which the Subcommittee noted was “misleading” and “raises questions about what [Plum’s] other thresholds actually are, and whether they exist.”<sup>20</sup> In fact, HBBF’s independent testing has confirmed the presence of Toxic Heavy Metals in Plum’s baby food.<sup>21</sup>

43. While Sprout did not respond to the Subcommittee’s request at all, the independent testing conducted by HBBF confirmed that Sprout’s Baby Foods are similarly tainted by substantial amounts of Toxic Heavy Metals.<sup>22</sup>

### ***Defendants’ Baby Food***

44. Defendants manufacture, distribute, advertise, market, and sell brands of baby food, and direct, control, and participate in the manufacturing and packaging of the baby food products that they sell. As part of that direction, control, and participation, Defendants determine and are responsible for the ingredients used in their baby food.

45. Defendants know and are responsible for the ingredients in their baby food products that they sell.

46. Defendants created, developed, reviewed, authorized, and are responsible for the textual and graphic content on the packaging of the baby food products that they sell. The labels on Defendants’ Baby Foods contain their standardized labels created, developed, reviewed, and authorized by Defendants. Defendants knew, created, developed, reviewed and are responsible for the representations contained on each package of baby food that they sell.

47. Defendants intended to induce reasonable consumers to rely on their marketing, all of which explicitly and implicitly convey that Defendants’ baby foods are healthy for consumption by babies. Such marketing include words written on the containers of Defendants’ baby foods, including, but not limited to, the following words and phrases: “Organic,” “Naturals,” “Nothing Artificial Added,” “Organic Baby Food,” “Made with Real Ingredients,”

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<sup>20</sup> Subcommittee Report at p. 45.

<sup>21</sup> HBBF Report at pp. 22-31.

<sup>22</sup> *Id.*

“No Artificial Colors, Flavors or Preservatives,” “BPA-Free Packaging,” “Non-GMO” (which stands for “genetically modified organism” which are also associated with health risks), etc.

Below are some examples:



1           48.     Plaintiffs justifiably relied on Defendants' marketing and suffered damages when  
2 they unknowingly purchased baby foods that contain toxic heavy metals and other undesirable  
3 toxins and contaminants. Additionally, the minor Plaintiffs were harmed or placed at risk of  
4 harm by consuming foods containing Toxic Heavy Metals and other undesirable toxins and  
5 contaminants.

6           49.     Defendants' false and misleading advertising deceives consumers into believing  
7 that they are purchasing and feeding their babies safe and nutritious baby foods, and through  
8 this deception, Defendants seek to induce consumers to purchase Defendants' baby food when  
9 they would have otherwise purchased alternative baby foods had they known that Defendants'  
10 baby foods contain toxic heavy metals such as arsenic, lead, cadmium and mercury, all of which  
11 have been proven to cause harm in infants and children.

***Consumer Expectations Regarding Baby Food***

12           50.     Parents' instinctive desire to protect and ensure the healthy development of their  
13 children is well-known. As such, the safety of baby food is of paramount importance, and is  
14 a material fact, to consumers (such as Plaintiffs and Class members).

15           51.     More specifically, given the negative effects of Toxic Heavy Metals (such as  
16 arsenic, lead, cadmium, and mercury) on child development, the presence of these substances  
17 in baby food is a material fact to consumers (such as Plaintiffs and members of the Class). Indeed,  
18 consumers—such as Plaintiffs and members of the Class—are unwilling to purchase baby food  
19 that contains elevated levels of Toxic Heavy Metals.

20           52.     Defendants know that the safety of their brands of baby food (as a general matter)  
21 is a material fact to consumers. This is exemplified by the fact that Defendants' baby food  
22 products are marketed and labeled as *lacking* certain substances (*e.g.*, BPA, GMOs) that  
23 consumers believe would be deleterious to the health of children.

24           53.     Defendants also know that consumers (such as Plaintiffs and members of the  
25 Class) are unwilling to purchase their baby food products that contain elevated levels of  
26 Toxic Heavy Metals.

27           54.     As such, Defendants also know that the presence of Toxic Heavy Metals in their  
28 baby food products is a material fact to consumers (such as Plaintiffs and Class members).

          55.     Baby food manufacturers (such as Defendants) hold a special position of public

1 trust. Consumers believe that they would not sell products that are unsafe to their infants.<sup>23</sup>

2 56. Defendants knew that if the elevated levels of Toxic Heavy Metals in their baby  
3 food products was disclosed to Plaintiffs and Class members, then Plaintiffs and Class members  
4 would be unwilling to purchase Defendants' Baby Foods.

5 57. In light of Defendants' knowledge that Plaintiffs and Class members would  
6 be unwilling to purchase baby food if they knew that their baby food products contained elevated  
7 levels of Toxic Heavy Metals, Defendants intentionally and knowingly concealed these facts  
8 from Plaintiffs and Class members, and did not disclose the presence of these Toxic Heavy  
9 Metals on the labels of Defendants' baby food products.

10 58. Defendants knew that Plaintiffs and Class members would rely upon the  
11 representations and omissions contained on the packages of Defendants' baby food products, and  
12 intended for them to do so.

13 59. Defendants knew that in relying upon the representations and omissions  
14 contained on the packages of Defendants' baby food products, Plaintiffs and Class members  
15 would view those products as being safe for consumption, given their represented lack of certain  
16 substances (*e.g.*, BPA, GMOs), and Defendants' concealment of the fact that baby food products  
17 contained elevated levels of Toxic Heavy Metals.

18 60. Prior to purchasing Defendants' baby food products, Plaintiffs and Class members  
19 were exposed to, saw, read, and understood Defendants' representations and omissions regarding  
20 the safety of their baby food products, and relied upon them.

21 61. As a result of Defendants' representations regarding the safety of its baby food, and  
22 the lack of certain deleterious substances (*e.g.*, BPA, GMOs), and Defendants' concealment of  
23 the fact that their brands of baby food contained elevated levels of Toxic Heavy Metals,  
24 Plaintiffs and Class members reasonably believed that Defendants' baby food products were  
25 free from substances that would negatively affect children's development.

26 62. In reliance upon Defendants' representations and omissions, Plaintiffs and Class  
27 members purchased Defendants' baby food products.

28 63. Had Plaintiffs and Class members known the truth—*i.e.*, that Defendants' brand  
of baby food products contained elevated levels of Toxic Heavy Metals, rendering them unsafe

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<sup>23</sup> Subcommittee Report at p. 6.



1 for consumption by children—they would not have been willing to purchase these products at  
2 all.

3 64. Therefore, as a direct and proximate result of Defendants’ misrepresentations  
4 and omissions concerning their baby food products, Plaintiffs and Class members purchased these  
5 products and were harmed given that the presence of elevated levels of Toxic Heavy Metals in  
6 baby food renders it unsafe for human consumption, and are especially harmful to infants and  
7 children who are the most vulnerable in society.

8 65. Plaintiffs bring this action on behalf of themselves, and Classes of similarly  
9 situated individuals, seeking recovery of damages, including actual damages, enhanced,  
10 statutory, and punitive damages, as well as equitable relief, including restitution, disgorgement,  
11 and injunctive relief, reasonable attorneys’ fees and costs, as allowed under the various causes of  
12 action set forth herein.

13 66. Plaintiffs are likely to consider purchasing baby food products in the future  
14 provided that Defendants institute corrective measures and cure their unfair and deceptive acts  
15 and practices. Should Defendants provide clear and non-misleading disclosures regarding the  
16 levels of Toxic Heavy Metals in their baby food products, improve their sourcing of  
17 ingredients and manufacturing processes, and accurately and effectively test final products of  
18 their baby food products for excessive levels of Toxic Heavy Metals, Plaintiffs would likely  
19 purchase baby food products from Defendants if they are truthfully labeled and do not contain  
20 excessive levels of Toxic Heavy Metals or other hazardous substances.

21 67. Additionally, Defendants are equitably estopped from asserting defenses  
22 relating to statutes of limitations. Not only did Defendants fail to disclose the elevated levels  
23 of Toxic Heavy Metals in their baby food products, but Defendants also touted their brands of  
24 baby food as wholesome, natural, specially prepared to meet nutritional and developmental needs  
25 of babies and children, and lacking certain undesired substances, such as BPA and GMOs, and  
26 including certain beneficial substances, such as iron. Defendants also omitted and concealed the  
27 facts regarding the presence of Toxic Heavy Metals from the FDA and Congress, and actively  
28 and fraudulently concealed and continue to conceal the true nature of the ingredients of their baby  
food products.

**CLASS ACTION ALLEGATIONS**

68. As further stated herein as to the following claims, Plaintiffs bring their causes of action on behalf of themselves and all others similarly situated, and certification of this class action is appropriate under California *Code of Civil Procedure* section 382 and California *Civil Code* section 1781, because the questions of law or fact common to the respective Class members predominate over questions of law or fact affecting only individual members.

The “Class” is defined as all persons or entities who, within the State of California, from September 2009 through December 2021 (the “Class Period”), who purchased and/or consumed the subject Baby Foods from Beech-Nut Nutrition Company, Nurture, Inc. (which sells baby foods under the brand name HappyBABY), Plum Inc. d.b.a. Plum Organics, Gerber Products Company, Walmart, Inc. (which sells Baby Foods under the brand name Parent’s Choice), and Sprout Foods, Inc., which contain high levels of toxic heavy metals including mercury, lead, arsenic and cadmium.

69. Excluded from the Class are Defendants’ officers, employees, agents or affiliates, and any judge who presides over this action, as well as past and present employees, officers and directors of Defendants. Plaintiffs reserve the right to expand, limit, modify, or amend this Class definition, including the addition of one or more subclasses, in connection with their motion for class certification, or at any other time, based upon, inter alia, changing circumstances and/or new facts obtained during discovery.

**A. Commonality**

70. There are questions of law and fact that are common to the claims of Plaintiffs. Among these common questions are the following:

a. Whether Defendants violated California’s Unfair Competition Law by knowingly formulating, manufacturing, advertising, and selling baby foods touted as healthy, nutritious and safe for consumption when, in reality, the baby foods contain toxic heavy metals;

(b) Whether Defendants violated California’s Unfair Competition Law by misrepresenting material information to consumers regarding Defendants’ baby food products and their ability to be nutritious to a baby’s diet;

(c) Whether Defendants violated California’s Unfair Competition Law



1 by concealing material information from consumers regarding the fact that the baby foods  
 2 contain high levels of toxic heavy metals, so that consumers would not know that the baby  
 3 foods pose a health risk to babies and their development;

4 (d) Whether Defendants violated California's Unfair Competition Law  
 5 by using uniform, deceptive business practices, such as telling consumers via their websites that  
 6 the baby foods involved are safe to consume and have undergone thorough testing, without  
 7 transparently disclosing Defendant's testing standards and ultimate results;

8 (e) Whether Defendants represented and continue to represent that their  
 9 baby foods are of a particular standard, quality, or grade when they are not;

10 (f) Whether Defendants advertised their Baby Foods with the intent not to  
 11 sell them as advertised;

12 (g) Whether Defendants owed a duty of care to their customers to ensure  
 13 that their baby foods do not contain any toxic heavy metals or other undesirable toxins or  
 14 contaminants;

15 (h) Whether Defendants owed a duty to investigate that their baby foods do  
 16 not contain any toxic heavy metals or other undesirable toxins or contaminants; and

17 (i) Whether Defendants' conduct as set forth above injured consumers, and if so,  
 18 the extent of the injury.

## 19 **B. Numerosity**

20 (j) The members of the Class are so numerous that separate joinder of each  
 21 member is impracticable. Plaintiffs are informed and believe that in the County of Los Angeles  
 22 alone, the members of the Class would easily exceed the minimum numbers to satisfy this  
 23 requirement.

## 24 **C. Typicality**

25 (k) Plaintiffs' claims are typical of the claims of the Class because  
 26 Plaintiffs, like the other Class Members, purchased Defendants' baby foods based on the  
 27 reasonable belief that they were healthy, nutritious, and safe for consumption by babies. Plaintiffs,  
 28 as with other Class Members, were deceived by Defendants' misrepresentations and omissions  
 of fact.

(l) The core issues which predominate over all the other issues in the

litigation involve Defendants' unfair competition, violation of the CLRA and other violations, as discussed above.

(m) Upon information and belief, there has never been a prior lawsuit certified as a class on behalf of Plaintiffs based on the allegations in this Complaint.

#### **D. Adequacy of Representation**

(n) Plaintiffs will fairly and adequately protect the interests of the Class and are committed to the vigorous prosecution of this action. They have retained competent counsel, experienced in litigation of this nature, to represent them and members of the Class. There is no hostility between Plaintiffs and the unnamed Class members. Plaintiffs anticipate no difficulty in the management of this litigation as a class action.

(o) To prosecute this case, Plaintiffs have chosen the law firm of Beverly Hills Trial Attorneys, P.C., whose attorneys have represented plaintiffs in class actions and as private attorneys general in bringing public interest actions.

#### **E. Superiority**

(p) The questions of law or fact common to the claims of Plaintiffs and of each Class member predominate over any questions of law or fact affecting only individual members of the Class. All claims by named Plaintiffs and unnamed Class members are based on the same alleged "across the board" representations by Defendants and other acts constituting negligence, unfair competition under the UCL, and violation of Consumer Legal Remedies Act.

(q) Common issues predominate when as here, liability can be determined on a class-wide basis, even when there are some individualized damages.

(r) As a result, when determining whether common questions predominate, courts focus on the liability issue and if the liability issue is common to the class as in the case at bar, common questions are held to predominate over individual questions.

(s) Since all claims by named Plaintiffs and unnamed Class members are based on the same alleged "across the board" failures by Defendants and other unfair competition under the UCL, the predominance requirement needed for class action treatment is satisfied.

(t) A class action is superior to thousands of individual actions in part because of the non-exhaustive factors listed below:

- i. Joinder of all class members would create extreme hardship and inconvenience for the affected consumers because of their immense

geographical dispersion.

- ii. It is highly unlikely that individual Plaintiffs would shoulder the burden of this vast and complex litigation as many are simply too poor or uneducated about Defendants' actions to bring separate actions;
- iii. The interests of justice will be well served by resolving the common disputes of potential class members in one forum;
- iv. Individual suits would not be cost effective. The costs to individual Plaintiffs in a collective action are lowered through the pooling of resources and by limiting the controversy to one proceeding which efficiently resolves common issues of law and fact that arose from the same alleged activity; and
- v. The action is manageable as a class action; individual lawsuits are not economically maintainable as individual actions.

Defendants have also acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final declaratory relief with respect to the Class as a whole.

### **FIRST CAUSE OF ACTION**

#### **(Strict Products Liability – Failure To Warn)**

71. Plaintiffs incorporate by reference each allegation set forth in preceding paragraphs as if fully stated herein.

72. At all relevant times, Defendants engaged in the business of researching, testing, developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and promoting Baby Foods, which are defective and unreasonably dangerous to consumers, including Plaintiffs, because they do not contain adequate warnings or instructions concerning the dangerous toxic heavy metals they contain. These actions were under the ultimate control and supervision of Defendants. At all relevant times, Defendants registered, researched, manufactured, distributed, marketed, and sold Baby Foods and aimed at a consumer market.

73. Defendants researched, tested, developed, designed, manufactured, labeled, marketed, sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their Baby Foods, and in the course of same, directly advertised or marketed the products to consumers and end users, including Plaintiffs, and therefore had a duty to warn of the risks associated with the consumption of said Baby Foods.

1           74.     At all relevant times, Defendants had a duty to properly test, develop, design,  
2 manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply,  
3 provide proper warnings, and take such steps as necessary to ensure their Baby Foods did not  
4 cause users and consumers to suffer from unreasonable and dangerous risks. Defendants had a  
5 continuing duty to warn Plaintiff of dangers associated with Baby Foods. Defendants, as a  
6 manufacturer, seller, or distributor of food, are held to the knowledge of an expert in the field.

7           75.     At the time of manufacture, Defendants could have provided the warnings or  
8 instructions regarding the full and complete risks of Baby Foods because they knew or should  
9 have known of the unreasonable risks of harm associated with the use of and/or exposure to  
10 such products.

11           76.     At all relevant times, Defendants failed and deliberately refused to investigate,  
12 study, test, or promote the safety or to minimize the dangers to users and consumers of their  
13 product and to those who would foreseeably use or be harmed by Defendants' Baby Foods.

14           77.     Even though Defendants knew or should have known that Baby Foods posed a  
15 grave risk of harm, they failed to exercise reasonable care to warn of the dangerous risks  
16 associated with use and exposure to the products. The dangerous propensities of their products  
17 and the neurotoxic characteristic of toxic heavy metals contained in Defendants' Baby Foods, as  
18 described above, were known to Defendants, or Defendants could have reasonably known about  
19 them through appropriate research and testing by known methods, at the time they distributed,  
20 supplied or sold the product, and were not known to end users and consumers, such as  
21 Plaintiffs. The product warnings for Baby Foods in effect during the time period Plaintiff  
22 consumed Baby Foods were vague, incomplete or otherwise inadequate, both substantively and  
23 graphically, to alert consumers to the severe health risks associated with Baby Foods  
24 consumption.

25           78.     Defendants knew or should have known that their products created significant  
26 risks of serious bodily harm to consumers, as alleged herein, and Defendants failed to  
27 adequately warn or instruct consumers, i.e., the reasonably foreseeable users, of the risks of  
28 exposure to their products.

          79.     Defendants failed to warn and have wrongfully concealed information  
concerning the dangerous level of toxic heavy metals in their Baby Foods and the potential for

1 consumed Baby Foods to expose children to toxic heavy metals, and further, have made false  
2 and/or misleading statements concerning the safety of the subject Baby Foods.

3 80. At all relevant times, Defendants' Baby Foods reached the intended consumers,  
4 handlers, and users or other persons coming into contact with these products, including  
5 Plaintiffs, without substantial change in their condition as designed, manufactured, sold,  
6 distributed, labeled, and marketed by Defendants.

7 81. Plaintiffs were exposed to Defendants' Baby Foods without knowledge of their  
8 dangerous characteristics.

9 82. At all relevant times, Plaintiffs were exposed to Defendants' Baby Foods while  
10 using them for their intended or reasonably foreseeable purposes, without knowledge of their  
11 dangerous characteristics.

12 83. Plaintiffs could not have reasonably discovered the defects and risks associated  
13 with Baby Foods prior to or at the time of consuming said Baby Foods. Plaintiffs relied upon  
14 the skill, superior knowledge, and judgment of Defendants to know about and disclose serious  
15 health risks associated with using Defendants' products.

16 84. Defendants knew or should have known that the information disseminated with  
17 their Baby Foods were inadequate, failed to communicate adequate information on the dangers  
18 associated with the consumption of food containing heavy toxic metals, and failed to  
19 communicate warnings and instructions that were appropriate and adequate to render the  
20 products safe for their ordinary, intended and reasonably foreseeable uses.

21 85. The information that Defendants did provide or communicate failed to contain  
22 relevant warnings, hazards, and precautions that would have enabled consumers such as  
23 Plaintiff to avoid consuming the products. Instead, Defendants disseminated information that  
24 was inaccurate, false, and misleading, and which failed to communicate accurately or  
25 adequately the comparative severity, duration, and extent of the risk of injuries with use of  
26 and/or exposure to the subject Baby Foods, continued to aggressively promote the safety of  
27 their products, even after they knew or should have known of the unreasonable risks from use or  
28 exposure, and concealed, downplayed, or otherwise suppressed, through aggressive marketing  
and promotion, any information or research about the risks and dangers of consuming said Baby  
Foods.

1           86.     This alleged failure to warn is not limited to the information contained on Baby  
2 Foods labeling. The Defendants were able, in accord with federal law, to comply with relevant  
3 state law by disclosing the known risks associated with Baby Foods through other non-labeling  
4 mediums, i.e., promotion, advertisements, public service announcements, and/or public  
5 information sources. But the Defendants did not disclose these known risks through any  
6 medium. The ability to provide such warnings is not prohibited by any federal law.

7           87.     Had Defendants provided adequate warnings and instructions and properly  
8 disclosed and disseminated the risks associated with their Baby Foods, Plaintiffs could have  
9 avoided the risk of developing injuries and could have obtained or used alternative products.  
10 However, as a result of Defendants' concealment of the dangers posed by their Baby Foods,  
11 Plaintiffs could not have averted their injuries.

12           88.     Defendants' conduct, as described above, was reckless. Defendants risked the  
13 lives of babies and children, including Plaintiffs, with knowledge of the safety problems  
14 associated with Baby Foods, and suppressed this knowledge from the general public.  
15 Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public.  
16 Defendants' reckless conduct warrants an award of punitive damages.

17           89.     Defendants' lack of adequate warnings and instructions accompanying their  
18 Baby Foods were a substantial factor in causing Plaintiffs' injuries.

19           90.     As a direct and proximate result of the Defendants' failure to provide an  
20 adequate warning of the risks of Baby Foods, Plaintiffs have been injured.

## 21                   **SECOND CAUSE OF ACTION**

### 22                   **(Negligence – Failure to Warn)**

23           91.     Plaintiffs incorporates by reference each allegation set forth in preceding  
24 paragraphs as if fully stated herein.

25           92.     At all relevant times, Defendants engaged in the business of testing, developing,  
26 designing, manufacturing, marketing, selling, distributing, and promoting Baby Foods.  
27 Defendants knew or by the exercise of reasonable care should have known that their Baby  
28 Foods are not accompanied with adequate warnings given the presence of toxic heavy metals in  
them. These actions were under the ultimate control and supervision of Defendants.

          93.     Defendants researched, developed, designed, tested, manufactured, inspected,  
labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of

1 commerce their Baby Foods, and in the course of same, directly advertised or marketed the  
2 products to consumers and end users, including Plaintiffs, and therefore had a duty to warn of  
3 the risks associated with the use of Baby Foods.

4 94. At all relevant times, Defendants had a duty to properly test, develop, design,  
5 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide  
6 proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause  
7 users and consumers to suffer from unreasonable and dangerous risks. Defendants had a  
8 continuing duty to warn Plaintiffs of dangers associated with their Baby Foods. Defendants, as a  
9 manufacturer, seller, or distributor of food products, are held to the knowledge of an expert in  
10 the field.

11 95. At the time of manufacture, Defendants could have provided warnings regarding  
12 the full and complete risks of their Baby Foods containing toxic heavy metals because they  
13 knew or should have known that the consumption of their Baby Foods was dangerous, harmful  
14 and injurious when used by Plaintiffs in a reasonably foreseeable manner.

15 96. At all relevant times, Defendants failed and deliberately refused to investigate,  
16 study, test, or promote the safety or to minimize the dangers to users and consumers of their  
17 products and to those who would foreseeably use or be harmed by Defendants' Baby Foods.

18 97. Defendants knew or should have known that Baby Foods posed a grave risk of  
19 harm, but failed to exercise reasonable care to warn of the dangerous risks associated with use  
20 and exposure to the products. The dangerous propensities of their products and the  
21 characteristics of toxic heavy metals contained in substantial amounts in their Baby Foods, as  
22 described above, were known to Defendants, or should have been known to Defendants through  
23 appropriate research and testing by known methods, at the time they distributed, supplied or  
24 sold the products.

25 98. Defendants further breached their duty by failing to use reasonable care to  
26 adequately warn or instruct consumers (i.e., the reasonably foreseeable users) of the risks of  
27 exposure to their products. Defendants failed to warn and have wrongfully concealed  
28 information concerning the dangerous levels of toxic heavy metals in their Baby Foods and the  
potential for consumed Baby Foods to expose babies and toddlers to toxic heavy metals, and  
further, have made false and/or misleading statements concerning the safety of Baby Foods.



1           99. At all relevant times, Plaintiffs were exposed to excessive levels of toxic heavy  
2 metals through consumption of toxic heavy metals while using them for their intended or  
3 reasonably foreseeable, purposes, without knowledge of their dangerous characteristics.

4           100. Defendants knew or should have known that the minimal warnings disseminated  
5 with their Baby Foods were inadequate, failed to communicate adequate information on the  
6 dangers and safe use/exposure, and failed to communicate warnings and instructions that were  
7 appropriate and adequate to render the products safe for their ordinary, intended and reasonably  
8 foreseeable uses.

9           101. The information that Defendants did provide or communicate failed to contain  
10 relevant warnings, hazards, and precautions that would have enabled consumers such as  
11 Plaintiffs to avoid using the product. Instead, Defendants disseminated information that was  
12 inaccurate, false, and misleading, and which failed to communicate accurately or adequately the  
13 comparative severity, duration, and extent of the risk of injuries with use of and/or exposure to  
14 Baby Foods, continued to aggressively promote the efficacy of their products, even after they  
15 knew or should have known of the unreasonable risks from use or exposure, and concealed,  
16 downplayed, or otherwise suppressed, through aggressive marketing and promotion, any  
17 information or research about the risks and dangers of consuming Baby Foods.

18           102. A reasonable company under the same or similar circumstance would have  
19 warned and instructed of the dangers of these Baby Foods and the toxic heavy metals contained  
20 therein.

21           103. This alleged failure to warn is not limited to the information contained on the  
22 labeling of Defendants' Baby Foods. Defendants were able, in accord with federal law, to  
23 comply with relevant state law by disclosing the known risks associated with Baby Foods and  
24 toxic heavy metals through other non-labeling mediums, i.e., promotion, advertisements, public  
25 service announcements, and/or public information sources.

26           104. Had Defendants provided adequate warnings and instructions and properly  
27 disclosed and disseminated the risks associated with their Baby Foods, Plaintiffs could have  
28 avoided the risk of developing injuries and could have obtained or used alternative products.  
However, as a result of Defendants' concealment of the dangers posed by their Baby Foods,  
Plaintiffs could not have averted their injuries.



105. Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiffs, with knowledge of the safety problems associated with Baby Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an award of punitive damages.

106. The Defendants' lack of adequate warnings and instructions accompanying their Baby Foods were a substantial factor in causing Plaintiffs injuries.

107. As a direct and proximate result of the Defendants' failure to provide an adequate warning of the risks of Baby Foods, Plaintiffs have been injured.

### **THIRD CAUSE OF ACTION**

#### **(Negligent Product Design)**

108. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiffs would not have realized the potential risks and dangers of Baby Foods.

109. The Defendants owed a duty to all reasonably foreseeable users to design a safe product.

110. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods because the product exposed users, including Plaintiffs, to unsafe levels of toxic heavy metals.

111. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods by negligently designing the Baby Foods with ingredients and/or components high in toxic heavy metals.

112. The Defendants breached their duty by failing to use reasonable care in the design of Baby Foods by negligently designing and formulation, in one or more of the following ways:

- a. When placed in the stream of commerce, Defendants' Baby Foods were defective in design and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer would contemplate;
- b. When placed in the stream of commerce, Defendants' Baby Foods were unreasonably dangerous in that they were hazardous and posed a grave risk of neurodevelopmental disorders and other serious illnesses when used in a reasonably anticipated manner;

c. When placed in the stream of commerce, Defendants' Baby Foods contained unreasonably dangerous design defects and were not reasonably safe when used in a reasonably anticipated or intended manner;

d. Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically, the content of toxic heavy metals in the ingredients used to manufacture the foods and/or the finished products;

e. Defendants did not sufficiently test, investigate, or study their Baby Foods, specifically, the ability for their Baby Foods to expose babies to high amounts of toxic heavy metals;

f. Exposure to Baby Foods presents a risk of harmful effects that outweigh any potential utility stemming from the use of the products;

g. Defendants knew or should have known at the time of marketing their Baby Foods that exposure to toxic heavy metals contained in their Baby Foods could result in neurodevelopmental disorders such as ADHD---and other severe illnesses and injuries;

h. Defendants did not conduct adequate post-marketing surveillance of their Baby Foods; and

i. Defendants could have employed safer alternative designs and formulations, such as avoiding the use of ingredients high in toxic heavy metals.

113. The Defendants breached their duty by failing to use reasonable care by failing to use cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and safer alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods.

114. Additionally, a reasonable company under the same or similar circumstances would have designed a safer product.

115. Plaintiffs were harmed directly and proximately by Defendants' failure to use reasonable care in the design of their Baby Foods. Such harm includes significant exposure to toxic heavy metals, which can cause or contribute to the development of neurodevelopmental disorders such ADHD, as well as other illnesses.

116. Defendants' defective design of Baby Foods was willful, wanton, malicious, and conducted with reckless disregard for the health and safety of consumers of the Baby Foods, including Plaintiffs.

117. The defects in Defendants' Baby Foods were a substantial factor in causing Plaintiffs' injuries.

118. As a direct and proximate result of the Defendants' defective design of the Baby Foods, Plaintiffs have been injured and suffered damages.

#### **FOURTH CAUSE OF ACTION**

##### **(Negligent Manufacturing)**

119. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as if fully stated herein.

120. At all relevant times, the Defendants manufactured, tested, marketed, sold, and distributed the Baby Foods that Plaintiffs consumed.

121. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing, marketing, sale, and distribution of Baby Foods.

122. The Defendants knew or, by the exercise of reasonable care, should have known, these Baby Foods were carelessly manufactured, dangerous, harmful and injurious when used by Plaintiffs in a reasonably foreseeable manner.

123. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiffs would not have realized the potential risks and dangers of Baby Foods improperly manufactured, tested, marketed, distributed, and sold.

124. Without limitation, examples of the manner in which Defendants breached their duty to exercise reasonable care in manufacturing Baby Foods, included:

- a. Failure to adequately inspect/test the Baby Foods during the manufacturing process;
- b. Failure to implement procedures that would reduce or eliminate levels of toxic heavy metals in Baby Foods; and
- c. Failure to avoid using ingredients free from, or which contain far less, toxic heavy metals to manufacture Baby Foods.

125. Reasonable manufacturers under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality and safety of their products.

126. Plaintiffs were harmed directly and proximately by the Defendants' failure

1 to use reasonable care in the manufacture of their Baby Foods. Such harm includes significant  
 2 exposure to toxic heavy metals, which can cause or contribute the development of  
 3 neurodevelopmental disorders, such as ADHD, as well as other illnesses.

4 127. Defendants' improper manufacturing of Baby Foods was willful, wanton,  
 5 malicious, and conducted with reckless disregard for the health and safety of users of the Baby  
 6 Foods, including Plaintiffs.

7 128. The defects in Defendants' Baby Foods were substantial factors in causing  
 8 Plaintiffs injuries.

9 129. As a direct and proximate result of the Defendants' improper  
 10 manufacturing of Baby Foods, Plaintiffs have been injured.

### 11 **FIFTH CAUSE OF ACTION**

#### 12 **(Negligent Misrepresentation)**

13 130. Plaintiffs reallege and incorporate here by reference each of the foregoing  
 14 paragraphs, and further allege as follows.

15 131. At all relevant times, Defendants designed, manufactured, packaged,  
 16 labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed Baby  
 17 Foods into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing  
 18 harm to those that consumed Baby Foods, such as Plaintiff.

19 132 Defendants were negligent, reckless, and careless and owed a duty to  
 20 Plaintiff to make accurate and truthful representations regarding Baby Foods, Defendants  
 21 breached their duty, thereby causing Plaintiff to suffer harm.

22 133 Defendants represented to Plaintiffs via advertising, their websites,  
 23 packaging, promotions, as well as by other means, that their baby foods were both safe and  
 24 nutritious, when in fact, the baby food contained unsafe levels of toxic heavy metals far in excess  
 25 of regulatory standards. In fact, because of the presence of unsafe levels of toxic heavy metals in  
 26 Defendants' baby foods, the products presented an unacceptable risk of causing  
 27 neurodevelopmental disorders, such as ADHD, as well as other illnesses.

28 134. Additionally, Defendants represented to Plaintiffs that their baby foods were safe  
 for their intended use, when in fact, Defendants knew or should have known that their products

1 were not safe for their intended purpose and should not have been consumed by babies.  
 2 Defendants intended for Plaintiffs to rely on these representations and each of these  
 3 misrepresentations were material at the time they were made. In particular, each of the  
 4 misrepresentations concerned material facts that were essential to the analysis undertaken by  
 5 Plaintiffs as to whether they should purchase or consume these Baby Foods.

6 135. Defendants knew or should have known that their representations were false and  
 7 were negligently made without regard for their truth.

8 136. Plaintiffs reasonably placed their trust and reliance in Defendants' representations  
 9 that its baby foods were as advertised, that is that they were healthy, nutritious and safe for  
 10 consumption, and were harmed as described herein. Plaintiffs' reliance on Defendants'  
 11 representation was a substantial factor in causing Plaintiffs' harms.

12 137. Furthermore, Defendants' acts and omissions as described herein were committed  
 13 in reckless disregard of Plaintiffs' rights, interests, and well-being to enrich Defendants.  
 14 Defendants have yet to correct these misrepresentations about their baby foods.

15 138. Plaintiffs and the members of the class were injured as a direct and proximate  
 16 result of Defendants' negligent misrepresentations regarding their products, as described herein.

## 17 **SIXTH CAUSE OF ACTION**

### 18 **(Violation of *Business and Professions Code* sections 17200, *et seq.*)**

19 139. Plaintiffs reallege and incorporate here by reference each of the foregoing  
 20 paragraphs, and further allege as follows.

21 140. Plaintiffs, pursuant to *Business and Professions Code* section 17204, bring  
 22 this cause of action on behalf of themselves and as private attorneys general.

23 141. *Business and Professions Code* section 17200, *et seq.*, also known as the  
 24 Unfair Competition Law, defines "unfair business competition" to include any "unlawful, unfair  
 25 or fraudulent" act or practice, as well as any "unfair, deceptive, untrue or misleading" advertising.  
 26 The Unfair Competition Law imposes strict liability. Plaintiffs need not prove that Defendants  
 27  
 28

1 intentionally or negligently engaged in unlawful, unfair or fraudulent business practices – but  
 2 only that such practices occurred.

3 ***“Unlawful” Prong***

4 142. A business act or practice is “unlawful” under the UCL if it violates any  
 5 other law or regulation.

6 143. As detailed in Plaintiffs’ Cause of Action below, the Consumer Legal  
 7 Remedies Act, California *Civil Code* sections 1750 - 1784, prohibits a business from engaging in  
 8 sales practices that are deceptive or misrepresentations when offering goods and services to the  
 9 general public.

10 144. Defendants’ unlawful business practices are ongoing, and unless enjoined  
 11 under *Business & Professions Code* section 17203, and/or under section 17535, are likely to  
 12 continue to deceive other members of the general public at the expense of Defendants’  
 13 competitors.

14 145. Defendants violated Cal. Bus. & Prof. Code sections 17200, *et seq.* by engaging  
 15 in unlawful, unfair, or fraudulent business acts or practices and unfair, deceptive, untrue, or  
 16 misleading advertising, including:

- 17 a. Knowingly formulating, manufacturing, advertising, and selling baby foods  
 18 touted as healthy, nutritious and safe for consumption when, in reality, the baby  
 19 foods contain toxic heavy metals;
- 20 b. Misrepresenting material information to consumers regarding Defendant’s  
 21 baby food products and their ability to be nutritious to a baby’s diet;
- 22 c. Concealing material information from consumers regarding the fact that the  
 23 baby foods contain high levels of toxic heavy metals, so that consumers would  
 24 not know that the baby foods pose a health risk to babies and their development;  
 25 and
- 26 d. Using uniform, deceptive business practices, such as telling consumers via  
 27 their websites that the baby foods involved are safe to consume and have  
 28

undergone thorough testing, without transparently disclosing Defendant's testing standards and ultimate results.

***"Unfair" Prong***

146. A business act or practice is "unfair" under the UCL if it offends an established public policy or is immoral, unethical, oppressive, unscrupulous or substantially injurious to consumers, and that unfairness is determined by weighing the reasons, justifications and motives of the practice against the gravity of the harm to the alleged victims.

147. Defendants' business practices are unfair under the UCL because Defendants have acted in a manner that is immoral, unethical, oppressive, unscrupulous and/or substantially injurious to Plaintiffs and the Class Members. These business practices include failing to inform its customers about the true nature of their baby foods, and engaging in a pattern or practice of concealing those facts and urging their customers to purchase more of their baby foods based on the false belief that the foods remain safe to consume for babies, thereby depriving consumers of sufficient information to make an informed decision when purchasing baby food. Further, the impact of the practice against Plaintiffs and the Class Members far outweighs any possible justification or motive on the part of Defendants. The impact on Plaintiffs and the Class Members has been described. Defendants can have no possible justification for engaging in immoral, unethical and substantially injurious act of overcharging Plaintiffs and the Class Members through a misleading and deceptive conduct – selling baby foods that, in many instances, puts children at risk for severe developmental and health problems. Furthermore, Plaintiffs and the Class Members could not have reasonably avoided this injury because they relied on Defendants' advertising as to the quality and characteristics of the products being sold, as all consumers who rely on the verity of product advertising must do. Defendants' false advertising is also violative of public policy, as expressed in the CLRA.

148. Specifically, Plaintiffs' parents and guardians paid hefty prices overtime for Defendant's baby food products, believing that they were the most healthy options for growing children. Defendants have refused to admit that their products are indeed dangerous, and they

1 continue to market and sell their products in California. Defendants have engaged in this conduct  
 2 at the expense of their customers' rights as they could have easily informed their customers about  
 3 the actual contents of their products, but did not do so.

4 149. The harm to Plaintiffs and Class members outweighs the utility of  
 5 Defendants' practices. There were reasonably available alternatives to further Defendants'  
 6 legitimate business interests other than the misleading and deceptive conduct described herein.

7 ***"Fraudulent" Prong***

8 150. A business act or practice is "fraudulent" under the UCL if it is likely to  
 9 deceive members of the consuming public.

10 151. Defendants' acts and practices alleged above constitute fraudulent business  
 11 acts or practices as they have deceived Plaintiffs into purchasing and consuming certain baby  
 12 foods which contain high levels of high toxic metals, and are highly likely to deceive and have  
 13 deceived members of the consuming public.

14 152. Defendants' business practices, as alleged herein, also constitute fraudulent  
 15 conduct because Defendants did not deliver the products they advertised. Defendants'  
 16 representations and omissions in California were material because they were likely to deceive  
 17 reasonable consumers.

18 153. Plaintiffs and Class Members did not know that the baby foods contained  
 19 toxic heavy metals. Accordingly, Defendants should not have omitted and/or misrepresented the  
 20 facts surrounding the baby food's true contents.

21 154. Defendants omitted and misrepresented material information pertaining to  
 22 its baby foods' true contents to defraud Plaintiffs by, among other things, convincing Plaintiffs  
 23 and Class Members to purchase more of its products, and to otherwise ensure that Plaintiffs and  
 24 Class Members would not discover Defendant's underlying fraud regarding its omissions and  
 25 misrepresentations regarding the baby food products. As a result, Defendant violated Cal. Penal  
 26 Code § 502.  
 27

28 155. Defendants' fraud led to consumers paying for products that they would



1 not have paid for if they knew the truth about the fact that these products contained toxic  
2 heavy metals.

3 156. As a direct and proximate result of Defendants' unfair, unlawful, and  
4 fraudulent acts and practices, Plaintiffs and Class Members were injured and lost money. They  
5 did not receive the benefit of the bargain in purchasing the baby foods, and they spent their own  
6 time and money dealing with purchasing safer baby food alternatives. Additionally, Plaintiffs  
7 were harmed or placed at risk of imminent harm by consuming foods containing toxic heavy  
8 metals and other undesirable toxins and contaminants.

9 157. Defendants acted intentionally, knowingly, and maliciously in violation of  
10 California's Unfair Competition Law.

11 158. Plaintiffs and Class Members seek all monetary and non-monetary relief  
12 allowed by law, including restitution of all profits stemming from Defendants' unfair, unlawful,  
13 and fraudulent business practices, declaratory relief, reasonable attorneys' fees and costs under  
14 California Code of Civil Procedure § 1021.5, injunctive relief, and other appropriate equitable  
15 relief.

16 159. In prosecuting this action for the enforcement of important rights affecting  
17 the public interest, Plaintiffs also seek, in addition to damages, restitution and other equitable  
18 relief, to recover attorney fees under (i) section 1021.5 of the *Code of Civil Procedure*, and/or (ii)  
19 the "common fund" doctrine available to prevailing Plaintiffs who confer a benefit on the general  
20 public.

## 21 **SEVENTH CAUSE OF ACTION**

### 22 **(Violation of California *Civil Code* section 1750, *et seq.*)**

23 160. Plaintiffs reallege and incorporate here by reference each of the foregoing  
24 paragraphs, and further allege as follows.

25 161. Defendants are "persons" as defined by *Civil Code* section 1761(c).

26 162. Plaintiffs and each member of the Class are "consumers" within the meaning  
27 of *Civil Code* section 1761(d).  
28

1           163. The Consumers Legal Remedies Act applies to Defendants' conduct  
2 because it extends to transactions that are intended to or result in the sale or lease of goods or  
3 services to consumers. In accordance with the liberal application and construction of the CLRA,  
4 application of the CLRA to all class members is appropriate, given that Defendants' conduct as  
5 described herein originated from California, and consumers purchased or used the involved baby  
6 foods in California.

7           164. Defendants violated and continue to violate the CLRA by engaging in the  
8 following practices prescribed by *Civil Code* section 1770(a) in transactions with the members of  
9 the Class which were intended to result in, and did result in, the sale of products to Plaintiffs and  
10 the Class Members in violation of Civil Code section 1770, including: a) representing that goods  
11 or services have characteristics and uses that they do not have; b) representing that goods or  
12 services are of a particular standard, quality, or grade when they are not; c) advertising goods or  
13 services with intent not to sell them as advertised; and d) representing that the subject of a  
14 transaction has been supplied in accordance with a previous representation when it has not.  
15

16           165. Defendants' representations and omissions were material because they were  
17 likely to deceive reasonable consumers.

18           166. Had Defendants disclosed to Plaintiffs and Class Members that its baby  
19 foods contained toxic heavy metals, often times in amounts surpassing those recommended or  
20 deemed safe by multiple regulatory bodies, Plaintiffs and the Class Members would have made  
21 different purchasing decisions.

22           167. Had Defendants disclosed the truth, they would have been unable to  
23 continue in the same course of business. As such, Defendants represented that its baby foods  
24 were healthy, nutritious and safe for consumption by babies, who have been shown to be  
25 extremely susceptible to the harsh effects of exposure to toxic heavy metals. Plaintiffs and the  
26 Class Members acted reasonably in relying on Defendants' misrepresentations and omissions, the  
27 truth of which they could not have discovered.

28           168. As a direct and proximate result of Defendants' violations of California

1 Civil Code § 1770, Plaintiffs and Class Members have suffered and will continue to suffer injury,  
 2 ascertainable losses of money or property, and monetary and non-monetary damages. Such  
 3 monetary and non-monetary damages have arisen from not receiving the benefit of the bargain in  
 4 purchasing Defendants' baby foods, and increased time and expense in having to purchase safer  
 5 alternatives and to determine whether Plaintiffs have been negatively affected by consuming  
 6 Defendants' baby foods.

7 169. Pursuant to *Civil Code* section 1782(d), the Class seeks a court order  
 8 enjoining the above-described wrongful acts and practices of Defendants.

9 170. Pursuant to *Civil Code* section 1782, Plaintiffs notified Defendants in  
 10 writing by certified mail of the particular violations of Civil Code section 1770 and the other  
 11 violations as alleged herein and demanded that Defendants rectify the problems associated with  
 12 the actions detailed above and give notice to all affected consumers of its intent to so act.

#### 13 **EIGHTH CAUSE OF ACTION**

##### 14 **(Quasi-Contract/Unjust Enrichment)**

15 171. Plaintiffs reallege and incorporate here by reference each of the foregoing  
 16 paragraphs, and further allege as follows.

17 172. Plaintiffs and Class Members were enticed to purchase Defendants' Baby Foods,  
 18 which were not as Defendants represented them to be.

19 173. Had Plaintiffs and the Class known of the fact that the Baby Foods contained toxic  
 20 heavy metals such as arsenic, lead, cadmium, and/or mercury, they would not have purchased  
 21 Defendants' Baby Food, but would rather purchase baby foods manufactured by one of  
 22 Defendants' competitors.

23 174. Accordingly, Plaintiffs and Class Members were damaged, and Defendants were  
 24 unjustly enriched, given that they defrauded Plaintiffs into purchasing said baby food products by  
 25 not disclosing the fact that these products contained heavily toxic material.  
 26  
 27  
 28

175. Furthermore, Defendants' conduct was willful, intentionally deceptive, and intended to cause economic injury to Plaintiffs and the Class. Defendants are therefore liable to pay punitive damages.

176. Plaintiffs and Class Members are entitled to damages in the amount Defendant was unjustly enriched, to be determined at trial.

### **PRAYER FOR RELIEF**

177. Plaintiffs STACIA CULLORS, an individual, LAYLA CULLORS, NOELANI CULLORS and VIVIENNE CULLORS, through their guardian ad litem STACIA CULLORS, ANTHONY BACANI, an individual, DAHLIA BACANI and ELIAS BACANI, through their guardian ad litem ANTHONY BACANI, JENNIFER CULLORS, an individual, as well as AVA CULLORS and JOSHUA CULLORS, through their guardian ad litem JENNIFER CULLORS, and on behalf of all others similarly situated pray for relief and judgment against Defendants as follows:

(a) An order certifying the Class and designating STACIA CULLORS, an individual, LAYLA CULLORS, NOELANI CULLORS and VIVIENNE CULLORS, through their guardian ad litem STACIA CULLORS, ANTHONY BACANI, an individual, DAHLIA BACANI and ELIAS BACANI, through their guardian ad litem ANTHONY BACANI, JENNIFER CULLORS, an individual, as well as AVA CULLORS and JOSHUA CULLORS, through their guardian ad litem JENNIFER CULLORS as Class Representatives and their counsel as Class Counsel;

(b) Awarding Plaintiffs and the proposed Class members actual or compensatory damages according to proof;

(c) Awarding restitution and disgorgement of all profits and unjust enrichment that Defendants obtained from Plaintiffs and the Class members as a result of their unlawful, unfair and fraudulent business practices described herein;

(d) Awarding declaratory and injunctive relief as permitting by law or

1 equity to individual Plaintiffs, including enjoining Defendants from continuing the  
2 unlawful practices set forth herein, and directing Defendants to identify, with Court  
3 supervision, victims of their misconduct and pay them all money they are required to pay;

4 (e) Exemplary and punitive damages sufficient to punish and deter the  
5 Defendants and others from future wrongful practices;

6 (f) Pre-judgment and post-judgment interest;

7 (g) Awarding attorneys' fees and costs; and

8 (h) Providing such further relief as may be just and proper.  
9

10 **DEMAND FOR JURY TRIAL**

11 Plaintiffs demand trial by jury of all issues raised in this Complaint.  
12  
13

14 DATED: February 25, 2022

**BEVERLY HILLS TRIAL ATTORNEYS, P.C.**

15  
16 /s/ Azar Mouzari  
17 Azar Mouzari, Esq.  
18 Nilofar Nouri, Esq.  
19 Attorneys for Plaintiff  
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# EXHIBIT “A”



## **Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury**



### **Staff Report**

**Subcommittee on Economic and Consumer Policy  
Committee on Oversight and Reform  
U.S. House of Representatives**

**February 4, 2021**

**[oversight.house.gov](https://oversight.house.gov)**



## **EXECUTIVE SUMMARY**

Inorganic arsenic, lead, cadmium, and mercury are toxic heavy metals. The Food and Drug Administration and the World Health Organization have declared them dangerous to human health, particularly to babies and children, who are most vulnerable to their neurotoxic effects. Even low levels of exposure can cause serious and often irreversible damage to brain development.

On November 6, 2019, following reports alleging high levels of toxic heavy metals in baby foods, the Subcommittee on Economic and Consumer Policy requested internal documents and test results from seven of the largest manufacturers of baby food in the United States, including both makers of organic and conventional products:

- Nurture, Inc. (Nurture), which sells Happy Family Organics, including baby food products under the brand name HappyBABY
- Beech-Nut Nutrition Company (Beech-Nut)
- Hain Celestial Group, Inc. (Hain), which sells baby food products under the brand name Earth's Best Organic
- Gerber
- Campbell Soup Company (Campbell), which sells baby food products under the brand name Plum Organics
- Walmart Inc. (Walmart), which sells baby food products through its private brand Parent's Choice
- Sprout Foods, Inc. (Sprout Organic Foods)

Four of the companies—Nurture, Beech-Nut, Hain, and Gerber—responded to the Subcommittee's requests. They produced their internal testing policies, test results for ingredients and/or finished products, and documentation about what the companies did with ingredients and/or finished products that exceeded their internal testing limits.

Walmart, Campbell, and Sprout Organic Foods refused to cooperate with the Subcommittee's investigation. The Subcommittee is greatly concerned that their lack of cooperation might be obscuring the presence of even higher levels of toxic heavy metals in their baby food products than their competitors' products.

## **FINDINGS**

1. According to internal company documents and test results obtained by the Subcommittee, commercial baby foods are tainted with significant levels of toxic heavy metals, including arsenic, lead, cadmium, and mercury. Exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior in children. Toxic heavy metals endanger infant neurological development and long-term brain function. Specifically, the Subcommittee reports that:

**ARSENIC** was present in baby foods made by all responding companies.

- Nurture (HappyBABY) sold baby foods after tests showed they contained as much as 180 parts per billion (ppb) inorganic arsenic. Over 25% of the products Nurture tested before sale contained over 100 ppb inorganic arsenic. Nurture's testing shows that the typical baby food product it sold contained 60 ppb inorganic arsenic.
- Hain (Earth's Best Organic) sold finished baby food products containing as much as 129 ppb inorganic arsenic. Hain typically only tested its ingredients, not finished products. Documents show that Hain used ingredients testing as high as 309 ppb arsenic.
- Beech-Nut used ingredients after they tested as high as 913.4 ppb arsenic. Beech-Nut routinely used high-arsenic additives that tested over 300 ppb arsenic to address product characteristics such as "crumb softness."
- Gerber used high-arsenic ingredients, using 67 batches of rice flour that had tested over 90 ppb inorganic arsenic.

**LEAD** was present in baby foods made by all responding companies.

- Nurture (HappyBABY) sold finished baby food products that tested as high as 641 ppb lead. Almost 20% of the finished baby food products that Nurture tested contained over 10 ppb lead.
- Beech-Nut used ingredients containing as much as 886.9 ppb lead. It used many ingredients with high lead content, including 483 that contained over 5 ppb lead, 89 that contained over 15 ppb lead, and 57 that contained over 20 ppb lead.
- Hain (Earth's Best Organic) used ingredients containing as much as 352 ppb lead. Hain used many ingredients with high lead content, including 88 that tested over 20 ppb lead and six that tested over 200 ppb lead.
- Gerber used ingredients that tested as high as 48 ppb lead; and used many ingredients containing over 20 ppb lead.

**CADMIUM** was present in baby foods made by all responding companies.

- Beech-Nut used 105 ingredients that tested over 20 ppb cadmium. Some tested much higher, up to 344.55 ppb cadmium.
- Hain (Earth's Best Organic) used 102 ingredients in its baby food that tested over 20 ppb cadmium. Some tested much higher, up to 260 ppb cadmium.

- Sixty-five percent of Nurture (HappyBABY) finished baby food products contained more than 5 ppb cadmium.
- Seventy-five percent of Gerber's carrots contained cadmium in excess of 5 ppb, with some containing up to 87 ppb cadmium.

**MERCURY** was detected in baby food of the only responding company that tested for it.

- Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury.
- Beech-Nut and Hain (Earth's Best Organic) do not even test for mercury in baby food.
- Gerber rarely tests for mercury in its baby foods.

These results are multiples higher than allowed under existing regulations for other products. For example, the Food and Drug Administration has set the maximum allowable levels in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and 5 ppb cadmium, and the Environmental Protection Agency has capped the allowable level of mercury in drinking water at 2 ppb. The test results of baby foods and their ingredients eclipse those levels: including results up to 91 times the arsenic level, up to 177 times the lead level, up to 69 times the cadmium level, and up to 5 times the mercury level.

2. Internal company standards permit dangerously high levels of toxic heavy metals, and documents revealed that the manufacturers have often sold foods that exceeded those levels.
  - Nurture (HappyBABY) sold all products tested, regardless of how much toxic heavy metal the baby food contained. By company policy, Nurture's toxic heavy metal testing is not intended for consumer safety. The Food and Drug Administration (FDA) has only finalized one standard—100 ppb inorganic arsenic in infant rice cereal—and Nurture set its internal standard for that product 15% higher than the FDA limit, at 115 ppb.
  - Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. These standards are the highest of any responding manufacturer.
  - Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. But Hain exceeded its internal policies, using ingredients containing 353 ppb lead and 309 ppb arsenic. Hain justified deviations above its ingredient testing

standards based on “theoretical calculations,” even after Hain admitted to FDA that its testing underestimated final product toxic heavy metal levels.

3. The Subcommittee has grave concerns about baby food products manufactured by Walmart (Parent’s Choice), Sprout Organic Foods, and Campbell (Plum Organics). These companies refused to cooperate with the Subcommittee’s investigation. The Subcommittee is greatly concerned that their lack of cooperation might obscure the presence of even higher levels of toxic heavy metals in their baby food products, compared to their competitors’ products.
  - Walmart sells Parent’s Choice and Parent’s Choice Organic products for babies as young as four months.
  - Sprout Organic Foods sells organic products for babies as young as six months. It is owned by North Castle Partners, a Greenwich, Connecticut–based private equity firm.
  - Campbell sells Plum Organics products for babies as young as four months.
  - Independent testing of Walmart, Sprout Organic Foods, and Campbell products has confirmed that their baby foods contain concerning levels of toxic heavy metals.
4. The Trump administration ignored a secret industry presentation to federal regulators revealing increased risks of toxic heavy metals in baby foods. On August 1, 2019, FDA received a secret slide presentation from Hain (Earth’s Best Organic), which revealed that:
  - Corporate policies to test only ingredients, not final products, underrepresent the levels of toxic heavy metals in baby foods. In 100% of the Hain baby foods tested, inorganic arsenic levels were higher in the finished baby food than the company estimated they would be based on individual ingredient testing. Inorganic arsenic was between 28% and 93% higher in the finished products;
  - Many of Hain’s baby foods were tainted with high levels of inorganic arsenic—half of its brown rice baby foods contained over 100 ppb inorganic arsenic; its average brown rice baby food contained 97.62 ppb inorganic arsenic; and
  - Naturally occurring toxic heavy metals may not be the only problem causing the unsafe levels of toxic heavy metals in baby foods; rather, baby food producers like Hain may be adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.

This presentation made clear that ingredient testing is inadequate, and that only final product testing can measure the true danger posed by baby foods.

The Trump FDA took no new action in response. To this day, baby foods containing toxic heavy metals bear no label or warning to parents. Manufacturers are free to test only ingredients, or, for the vast majority of baby foods, to conduct no testing at all. FDA has only finalized one metal standard for one narrow category of baby food, setting a 100 ppb inorganic arsenic standard for infant rice cereal. But this FDA standard is far too high to protect against the neurological effects on children.

5. The Subcommittee makes the following recommendations:

- **Mandatory testing**—Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients;
- **Labeling**—Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels;
- **Voluntary phase-out of toxic ingredients**—Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals, or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice;
- **FDA standards**—FDA should set maximum levels of toxic heavy metals permitted in baby foods. One level for each metal should apply across all baby foods. And the level should be set to protect babies against the neurological effects of toxic heavy metals; and
- **Parental vigilance**—Parents should avoid baby foods that contain ingredients testing high in toxic heavy metals, such as rice products. Instituting recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

6. Baby food manufacturers hold a special position of public trust. Consumers believe that they would not sell products that are unsafe. Consumers also believe that the federal government would not knowingly permit the sale of unsafe baby food. As this staff report reveals, baby food manufacturers and the Trump administration's federal regulators have broken the faith.

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## I. THE DANGER OF TOXIC HEAVY METALS TO CHILDREN'S HEALTH

Children's exposure to toxic heavy metals causes permanent decreases in IQ, diminished future economic productivity, and increased risk of future criminal and antisocial behavior.<sup>1</sup>

Babies' developing brains are "exceptionally sensitive to injury caused by toxic chemicals, and several developmental processes have been shown to be highly vulnerable to chemical toxicity."<sup>2</sup> The fact that babies are small, have other developing organ systems, and absorb more of the heavy metals than adults, exacerbates their risk from exposure to heavy metals.<sup>3</sup>

Exposure to heavy metals at this developmental stage can lead to "untreatable and frequently permanent" brain damage, which may result in "reduced intelligence, as expressed in terms of lost IQ points, or disruption in behavior."<sup>4</sup> For example, a recent study estimates that exposure to environmental chemicals, including lead, are associated with 40,131,518 total IQ points loss in 25.5 million children (or roughly 1.57 lost IQ points per child)—more than the total IQ losses associated with preterm birth (34,031,025), brain tumors (37,288), and traumatic brain injury (5,827,300) combined.<sup>5</sup> For every one IQ point lost, it is estimated that a child's lifetime earning capacity will be decreased by \$18,000.<sup>6</sup>

Well-known vectors of child exposure to toxic heavy metals include lead paint in old housing and water pollution from landfills. Over the decades, a range of federal and state laws and regulations have been passed to protect child health through emissions standards, among other things.

The Food and Drug Administration (FDA) has declared that inorganic arsenic, lead, cadmium, and mercury are dangerous, particularly to infants and children. They have "no established health benefit" and "lead to illness, impairment, and in high doses, death." According to FDA, "even low levels of harmful metals from individual food sources, can

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<sup>1</sup> Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (Apr. 9, 2013) (online at [www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub](http://www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub)).

<sup>2</sup> Philippe Grandjean and Philip J. Landrigan, *Neurobehavioural Effects of Developmental Toxicity* (Mar. 13, 2014) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/)).

<sup>3</sup> Consumer Reports, *Heavy Metals in Baby Food: What You Need to Know* (Aug. 16, 2018) (online at [www.consumerreports.org/food-safety/heavy-metals-in-baby-food/](http://www.consumerreports.org/food-safety/heavy-metals-in-baby-food/)).

<sup>4</sup> Philippe Grandjean and Philip J. Landrigan, *Neurobehavioural Effects of Developmental Toxicity* (Mar. 13, 2014) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4418502/)).

<sup>5</sup> David C. Bellinger, *A Strategy for Comparing the Contributions of Environmental Chemicals and Other Risk Factors to Neurodevelopment of Children* (Dec. 19, 2011) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC3339460/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3339460/)).

<sup>6</sup> Martine Bellanger et al., *Economic Benefits of Methylmercury Exposure Control in Europe: Monetary Value of Neurotoxicity Prevention* (Jan. 17, 2013) (online at <https://pubmed.ncbi.nlm.nih.gov/23289875/>).

sometimes add up to a level of concern.” FDA cautions that infants and children are at the greatest risk of harm from toxic heavy metal exposure.<sup>7</sup>

The Subcommittee on Economic and Consumer Policy’s investigation has found another source of exposure: baby foods. According to documents obtained from baby food manufacturers, toxic heavy metals, such as arsenic, cadmium, lead, and mercury are present at substantial levels in both organic and conventional baby foods. Currently, there is no federal standard on, or warning to parents and caregivers about, these toxins.

#### A. Inorganic Arsenic

Arsenic is ranked number one among substances present in the environment that pose the most significant potential threat to human health, according to the Department of Health and Human Services’ Agency for Toxic Substances and Disease Registry (ATSDR).<sup>8</sup> The known health risks of arsenic exposure include “respiratory, gastrointestinal, haematological, hepatic, renal, skin, **neurological and immunological effects, as well as damaging effects on the central nervous system and cognitive development in children.**”<sup>9</sup>

Studies have concluded that arsenic exposure has a “significant negative effect on neurodevelopment in children.”<sup>10</sup> This negative effect is most pronounced in Full Scale IQ, and more specifically, in verbal and performance domains as well as memory. For every 50% increase in arsenic levels, there is an approximately “0.4 decrease in the IQ of children.”<sup>11</sup>

A study of Maine schoolchildren exposed to arsenic in drinking water found that children exposed to water with an arsenic concentration level greater than 5 parts per billion (ppb) “showed significant reductions in Full Scale IQ, Working Memory, Perceptual Reasoning and Verbal Comprehension scores.” The authors pegged 5 ppb as an important threshold.<sup>12</sup>

Likewise, a study of children in Spain found that increasing arsenic exposure led to a decrease in the children’s global motor, gross motor, and fine motor function scores. Boys in particular were more susceptible to arsenic’s neurotoxicity.<sup>13</sup>

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<sup>7</sup> Food and Drug Administration, *Metals and Your Food* (online at [www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food](http://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food)) (accessed Jan. 26, 2021).

<sup>8</sup> Agency for Toxic Substances and Disease Registry, *ATSDR’s Substance Priority List* (2019) (online at [www.atsdr.cdc.gov/spl/index.html#2019spl](http://www.atsdr.cdc.gov/spl/index.html#2019spl)).

<sup>9</sup> Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (June 1, 2013) (online at <https://pubmed.ncbi.nlm.nih.gov/23570911/>) (emphasis added).

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

<sup>12</sup> Gail A. Wasserman et al., *A Cross-Sectional Study of Well Water Arsenic and Child IQ in Maine Schoolchildren* (Apr. 1, 2014) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-23>).

<sup>13</sup> Antonio J. Signes-Pastor et al., *Inorganic Arsenic Exposure and Neuropsychological Development of Children of 4-5 Years of Age Living in Spain* (Apr. 29, 2019) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC6541502/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC6541502/)).

## B. Lead

Lead is number two on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.<sup>14</sup> Even small doses of lead exposure are hazardous, particularly to children.<sup>15</sup> Lead is associated with a range of bad health outcomes, including behavioral problems, decreased cognitive performance, delayed puberty, and reduced postnatal growth. According to FDA, lead is especially dangerous to "infants" and "young children." FDA acknowledges that:

High levels of lead exposure can seriously harm children's health and development, specifically the brain and nervous system. Neurological effects from high levels of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time.<sup>16</sup>

Lead exposure severely affects academic achievement in children. Even at low levels, early childhood lead exposure has a negative impact on school performance. Two separate studies of schoolchildren in Detroit and Chicago public schools found a strong inverse relationship between lead exposure and test scores. In the Detroit study, there was a "significant association" between early childhood lead exposure and decreased standardized test performance, with lead exposure strongly linked to an adverse effect on academic achievement.<sup>17</sup> The Chicago study found that higher blood lead concentrations were associated with lower reading and math scores in 3rd grade children. Increased blood lead concentrations correlated with a 32% increase in the risk of failing reading and math.<sup>18</sup>

The cognitive effects of early childhood lead exposure appear to be permanent. In one study, adults who previously had lead-associated developmental delays continued to show persisting cognitive deficits, demonstrating the long-lasting damage of lead exposure.<sup>19</sup>

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<sup>14</sup> Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at [www.atsdr.cdc.gov/spl/index.html#2019spl](http://www.atsdr.cdc.gov/spl/index.html#2019spl)).

<sup>15</sup> Philippe Grandjean, *Even Low-Dose Lead Exposure Is Hazardous* (Sept. 11, 2010) (online at <https://pubmed.ncbi.nlm.nih.gov/20833288/>).

<sup>16</sup> Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at [www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements](http://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>17</sup> Nanhua Zhang et al., *Early Childhood Lead Exposure and Academic Achievement: Evidence From Detroit Public Schools* (Mar. 2013) (online at <http://mediad.publicbroadcasting.net/p/michigan/files/201302/AJPH.2012.pdf>).

<sup>18</sup> Anne Evens et al., *The Impact of Low-Level Lead Toxicity on School Performance Among Children in the Chicago Public Schools: A Population-Based Retrospective Cohort Study* (Apr. 7, 2015) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-015-0008-9>).

<sup>19</sup> Maitreyi Mazumdar et al., *Low-Level Environmental Lead Exposure in Childhood and Adult Intellectual Function: A Follow-Up Study* (Mar. 30, 2011) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC3072933/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3072933/)).

Studies have also established a significant association between lead exposure and Attention-Deficit/Hyperactivity Disorder (ADHD).<sup>20</sup>

### C. Cadmium

Cadmium is number seven on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.<sup>21</sup> Cadmium is associated with decreases in IQ, as well as the development of ADHD.

A 2018 study found that cadmium exposure negatively affected children's Full Scale IQ, particularly among boys. Boys exhibiting higher amounts of cadmium exposure had seven fewer IQ points than those exhibiting less cadmium exposure.<sup>22</sup> A 2015 study similarly found a significant inverse relationship between early cadmium exposure and IQ.<sup>23</sup>

A 2018 study linked cadmium exposure to ADHD, finding that the disorder was more common among children with the highest levels of cadmium exposure as compared to a control group.<sup>24</sup>

### D. Mercury

Mercury is number three on ATSDR's list of substances present in the environment that pose the most significant potential threat to human health.<sup>25</sup> Studies of mercury's effect on childhood development have primarily been conducted by considering the mother's exposure to mercury while pregnant. In these instances, "pre-natal mercury exposure has been consistently associated with adverse subsequent neuro-development."<sup>26</sup> And pre-natal mercury exposure is also related to poorer estimated IQ.<sup>27</sup> Beyond prenatal exposure, higher blood mercury levels at

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<sup>20</sup> Gabriele Donzelli et al., *The Association Between Lead and Attention-Deficit/Hyperactivity Disorder: A Systematic Review* (Jan. 29, 2019) (online at [www.mdpi.com/1660-4601/16/3/382/htm](http://www.mdpi.com/1660-4601/16/3/382/htm)).

<sup>21</sup> Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at [www.atsdr.cdc.gov/spl/index.html#2019spl](http://www.atsdr.cdc.gov/spl/index.html#2019spl)).

<sup>22</sup> Klara Gustin et al., *Cadmium Exposure and Cognitive Abilities and Behavior at 10 Years Off Age: A Prospective Cohort Study* (Apr. 2018) (online at [www.sciencedirect.com/science/article/pii/S0160412017321025](http://www.sciencedirect.com/science/article/pii/S0160412017321025)).

<sup>23</sup> Alison P. Sanders et al., *Perinatal and Childhood Exposure To Cadmium, Manganese, And Metal Mixtures And Effects On Cognition And Behavior: A Review Of Recent Literature* (July 5, 2015) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC4531257/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4531257/)).

<sup>24</sup> Min-Jing Lee et al., *Heavy Metals' Effect on Susceptibility to Attention-Deficit/Hyperactivity Disorder: Implication of Lead, Cadmium, and Antimony* (June 10, 2018) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC6025252/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC6025252/)).

<sup>25</sup> Agency for Toxic Substances and Disease Registry, *ATSDR's Substance Priority List* (2019) (online at [www.atsdr.cdc.gov/spl/index.html#2019spl](http://www.atsdr.cdc.gov/spl/index.html#2019spl)).

<sup>26</sup> Margaret R. Karagas et al., *Evidence on the Human Health Effects of Low-Level Methylmercury Exposure* (June 1, 2012) (online at <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1104494>).

<sup>27</sup> Joseph Jacobson et al., *Relation of Prenatal Methylmercury Exposure from Environmental Sources to Childhood IQ* (Aug. 1, 2015) (online at <https://ehp.niehs.nih.gov/doi/10.1289/ehp.1408554>).

“2 and 3 years of age were positively associated with autistic behaviors among preschool-age children.”<sup>28</sup>

## **II. TOP BABY FOODS ARE TAINTED WITH DANGEROUS LEVELS OF INORGANIC ARSENIC, LEAD, CADMIUM, AND MERCURY.**

Internal company test results obtained by the Subcommittee confirm that all responding baby food manufacturers sold baby foods tainted by high levels of toxic heavy metals.

### **A. Inorganic Arsenic**

There is no established safe level of inorganic arsenic consumption for babies. Organizations such as Healthy Babies Bright Futures have called for a goal of no measurable amount of inorganic arsenic in baby food.<sup>29</sup> Consumer Reports suggests setting inorganic arsenic levels as low as 3 parts per billion (ppb).<sup>30</sup> FDA has already set maximum inorganic arsenic levels at 10 ppb for bottled water.<sup>31</sup> The Environmental Protection Agency (EPA) has similarly set a 10 ppb inorganic arsenic cap on drinking water, as have the European Union (EU) and the World Health Organization (WHO).<sup>32</sup>

#### **1. Nurture (HappyBABY) sold finished baby foods after testing showed they contained as much as 180 ppb inorganic arsenic; over 25% of the tested baby food sold by Nurture exceeded 100 ppb inorganic arsenic; on average, Nurture baby food on store shelves has nearly 60 ppb inorganic arsenic.**

Nurture is the only baby food manufacturer that appears to regularly tests its finished baby food products for inorganic arsenic content (the others only test ingredients).

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<sup>28</sup> Jia Ryu et al., *Associations of Prenatal and Early Childhood Mercury Exposure with Autistic Behaviors at 5 Years of Age: The Mothers and Children's Environmental Health (MOCEH) Study* (Dec. 15, 2017) (online at [www.sciencedirect.com/science/article/pii/S0048969717316479](http://www.sciencedirect.com/science/article/pii/S0048969717316479)).

<sup>29</sup> Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at [www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport\\_FULLREPORT\\_ENGLISH\\_R5b.pdf](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

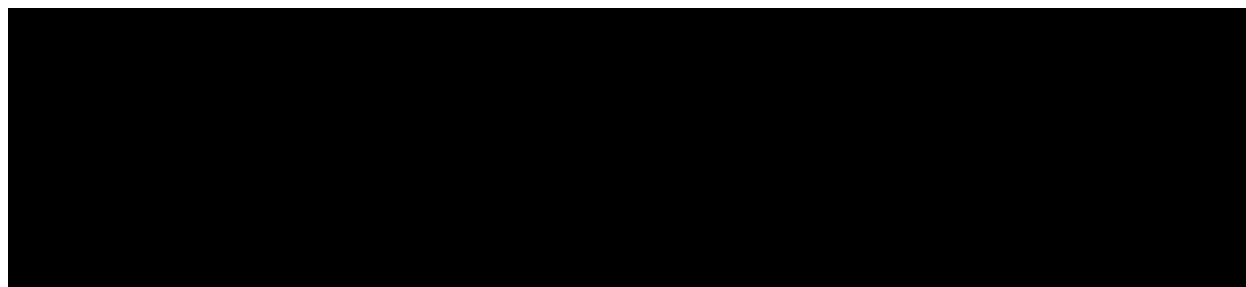
<sup>30</sup> Consumer Reports, *Arsenic in Some Bottled Water Brands at Unsafe Levels, Consumer Reports Says* (June 28, 2019) (online at [www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/](http://www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/)); Consumer Reports, *Arsenic and Lead Are in Your Fruit Juice: What You Need to Know* (Jan. 30, 2019) (online at [www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/](http://www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/)).

<sup>31</sup> Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at [www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements](http://www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>32</sup> Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at [www.epa.gov/dwreginfo/chemical-contaminant-rules](http://www.epa.gov/dwreginfo/chemical-contaminant-rules)) (accessed Jan. 26, 2021); The European Food Information Council, *Arsenic (Q&A)* (online at [www.eufic.org/en/food-safety/article/arsenic-qa](http://www.eufic.org/en/food-safety/article/arsenic-qa)) (accessed Jan. 26, 2021); World Health Organization, *Arsenic* (Feb. 15, 2018) (online at [www.who.int/news-room/fact-sheets/detail/arsenic](http://www.who.int/news-room/fact-sheets/detail/arsenic)).

According to internal company documents, Nurture sells products even after testing confirms that they are dangerously high in inorganic arsenic. Nurture sold one such product, Apple and Broccoli Puffs, despite tests results showing it contained 180 ppb inorganic arsenic.<sup>33</sup> An arsenic level of 180 ppb is high by all standards, but it is 80% higher than Nurture's own internal goal threshold of 100 ppb.

***Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)***<sup>34</sup>



Nurture routinely sold products that exceeded its internal standards. Twenty-nine other products that Nurture tested and sold registered over 100 ppb inorganic arsenic. In total, over 25% of the products that Nurture tested for inorganic arsenic, and sold, had inorganic arsenic levels above 100 ppb.<sup>35</sup>

***Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)***<sup>36</sup>

Product Name	Goal Threshold	Result	Date of Test Report	Disposition
Apple & Broccoli Puffs	100	180	11/01/17	Sell
Banana & Pumpkin Puffs	100	160	10/31/17	Sell
Strawberry & Beet Puffs	100	160	10/31/17	Sell
Kale & Spinach Puffs	100	150	10/31/17	Sell
Kale & Spinach Puffs	100	150	10/31/17	Sell
Purple Carrot & Blueberry Puffs	100	150	11/17/17	Sell
Sweet Potato & Carrot Puffs	100	150	10/31/17	Sell
Sweet Potato & Carrot Puffs	100	150	10/31/17	Sell
Apple Rice Cakes	100	130	02/08/17	Sell
Apple Rice Cakes	100	130	02/08/17	Sell
Sweet Potato & Carrot Puffs	100	122	09/13/18	Sell
Apple Rice Cakes	100	120	02/08/17	Sell

<sup>33</sup> Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*



Blueberry Beet Rice Cakes	100	120	02/08/17	Sell
Purple Carrot & Blueberry Puffs	100	120	10/31/17	Sell
Apple & Broccoli Puffs	100	115	10/15/18	Sell
Strawberry & Beet Puffs	100	114	03/21/19	Sell
Purple Carrot & Blueberry Puffs	100	112	06/05/18	Sell
Apple Rice Cakes	100	110	07/28/17	Sell
Blueberry Beet Rice Cakes	100	110	02/08/17	Sell
Blueberry Beet Rice Cakes	100	110	02/08/17	Sell
Strawberry & Beet Puffs	100	108	12/10/18	Sell
Strawberry & Beet Puffs	100	108	09/21/18	Sell
Apple & Broccoli Puffs	100	107	05/30/19	Sell
Strawberry & Beet Puffs	100	107	05/22/19	Sell
Strawberry & Beet Puffs	100	105	09/21/18	Sell
Strawberry & Beet Puffs	100	104	08/22/18	Sell
Banana & Pumpkin Puffs	100	103	04/24/19	Sell
Sweet Potato & Carrot Puffs	100	103	04/24/19	Sell
Banana & Pumpkin Puffs	100	101	09/21/18	Sell

The average amount of inorganic arsenic in the baby foods that Nurture tested and sold was 59.54 ppb. That towers over existing and recommended standards, including FDA's and EPA's water limits of 10 ppb.

At least 89 of Nurture's final products—over 78% of those products tested—tested at 9 ppb inorganic arsenic or above.

For results under 9.54 ppb, Nurture did not differentiate—it marked them all as “<9.54.” Because of this “less than” reporting format, there is no way to know if any of Nurture's products were free of inorganic arsenic.

### *Summary of Nurture's Inorganic Arsenic Results*

<b>180 ppb – Nurture's product with the highest amount of inorganic arsenic: Apple &amp; Broccoli Puffs.</b>
<b>&gt;100 ppb – Over 25% of the baby food products that were tested for inorganic arsenic had over 100 ppb inorganic arsenic.</b>
<b>59.54 ppb – Average amount of inorganic arsenic in all baby food products tested for inorganic arsenic.</b>
<b>&gt;50 ppb – Over 50% of Nurture's baby food products that were tested for inorganic arsenic contained over 50 ppb inorganic arsenic.</b>

2. **Hain (Earth's Best Organic) produced finished baby foods that contained as much as 129 ppb inorganic arsenic; Hain used ingredients in its baby foods with as much as 309 ppb total arsenic.**



Hain does not regularly test finished baby food products for inorganic arsenic content. It typically only tests ingredients. However, when Hain did test a small sample of finished product, it found 129 ppb inorganic arsenic.<sup>37</sup>

***Hain Celestial, FDA Testing Result Investigation, August 1, 2019 (Excerpted Entries)***<sup>38</sup>

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1024309	4/27/19	8N12216	129	129.0	93%	11/3/17	204146	B160005305	Total Arsenic	69	67.0
								B160005306	Total Arsenic	76	
								B160005512	Total Arsenic	62	
								B160005152	Total Arsenic	61	

The Subcommittee's review of the ingredient test results reveals that Hain routinely used ingredients with high levels of arsenic. Hain used brown rice flour that had tested at 309 ppb arsenic.<sup>39</sup> Hain likewise used a vitamin pre-mix containing 223 ppb arsenic, and raisin and wheat flour containing 200 ppb arsenic.<sup>40</sup> The testing data shows that Hain used at least 24 ingredients after testing found that they contained more than 100 ppb arsenic, its already-dangerously-high internal standard for most ingredients.<sup>41</sup>

***Hain, Raw Material Pre-Shipment Test Data History (Excerpted Entries)***<sup>42</sup>

Lab Results Date	Product Description	Status	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)
Jun/19/2019	Org Brown Rice Flour	Deviation Approved	100	309
Nov/26/2019	Vitamin Pre-Mix	Deviation Approved	100	223
Jul/10/2018	Org Whole Raisins	Accepted	100	200
Sep/29/2017	Org Soft White Wheat Flour	Accepted	200	200
Dec/14/2017	Org Spelt Flour	Accepted	100	190
Jan/8/2018	Organic Barley Malt Extract	Accepted	100	180
Dec/5/2017	Org Yellow Split Pea Powder	Accepted	100	160
Jul/13/2017	Medium Grain Whole Rice	Accepted	200	150
Oct/3/2017	Org Brown Rice Flour	Accepted	100	140
Sep/4/2019	Org Brown Rice Flour	Deviation Approved	100	134
Dec/5/2017	Org Butternut Squash Puree	Accepted	100	130
Oct/31/2017	Org Brown Rice Flour	Accepted	100	130

<sup>37</sup> Hain, *PowerPoint Presentation to FDA: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

<sup>38</sup> *Id.*

<sup>39</sup> Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

Oct/31/2017	Org Brown Rice Flour	Accepted	100	130
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	129
Oct/31/2017	Org Brown Rice Flour	Accepted	100	127
Oct/31/2017	Org Brown Rice Flour	Accepted	100	126
Dec/13/2017	Org Blueberry Puree	Accepted	100	120
Dec/27/2017	Org Barley Flour	Accepted	100	120
Oct/31/2017	Org Brown Rice Flour	Accepted	100	119
Nov/29/2017	Org Blueberry Puree	Accepted	100	110
Nov/3/2017	Org Cinnamon Powder	Accepted	100	110
Jul/11/2019	Org Brown Rice Flour	Accepted	100	101

**3. Beech-Nut used ingredients in its baby foods with as much at 913.4 ppb arsenic; Beech-Nut routinely used ingredients that exceeded 300 ppb total arsenic; Beech-Nut unnecessarily uses high-arsenic additives to address issues like “crumb softness.”**

Beech-Nut only tested arsenic content in its ingredients, not its final product. The Subcommittee has determined that Beech-Nut used ingredients containing as much as 913.4 ppb arsenic.<sup>43</sup> Test results show that Beech-Nut used at least fourteen other ingredients containing over 300 ppb arsenic.<sup>44</sup> And it used at least 45 ingredients containing over 100 ppb arsenic.

***Beech-Nut, Raw Material Heavy Metal Testing (Excerpted Entries)***<sup>45</sup>

Date	Commodity	Arsenic Result (ppb)	Spec.	Acceptance (Y/N)
9/19/2018	Amylase	913.40	N/A	Y
4/26/2018	Amylase	741.10	N/A	Y
10/7/2017	BAN 800	710.90	<3000	Y
11/29/2017	Alpha Amylase	679.00	N/A	Y
10/12/2017	Amylase	645.10	N/A	Y
8/20/2019	Sebamyl 100	583.60	N/A	Y
3/6/2018	Org. Rice Flour	570.00	≤100(inorg)	Y
6/7/2019	Enzyme	499.30	N/A	Y
12/20/2017	BAN 800	465.20	<3000	Y
1/14/2019	Enzyme	442.30	N/A	Y
10/23/2017	BAN 800	401.40	<3000	Y

<sup>43</sup> Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

2/19/2018	BAN 800	382.00	<3000	Y
6/12/2018	Ban 800	353.80	<3000	Y
5/21/2018	Org. Cumin	322.70	≤1000	Y
4/13/2018	Org. Rice	237.40	≤100(inorg)	Y
4/12/2018	Rice Flour	170.00	≤100(inorg)	Y
4/6/2018	Rice Flour	170.00	≤100(inorg)	Y
7/14/2017	Org. Cumin	168.50	≤1000	y
7/31/2018	rice flour	162.00	≤100(inorg)	Y
2/28/2018	Rice Flour	161.00	≤100(inorg)	y
3/30/2017	Cumin	160.50	≤1000	Y
3/27/2018	Rice Flour	160.00	≤100(inorg)	Y
5/30/2018	Rice Flour	160.00	≤100(inorg)	Y
6/12/2018	Rice Flour	160.00	≤100(inorg)	Y
7/20/2018	Rice Flour	160.00	≤100(inorg)	Y
10/11/2016	Oregano	158.10	<1000	Y
1/15/2018	Rice Flour	150.00	≤100(inorg)	Y
1/15/2018	Rice Flour	150.00	≤100(inorg)	Y
2/15/2018	Rice Flour	150.00	≤100(inorg)	Y
5/31/2018	Rice Flour	150.00	≤100(inorg)	Y
2/22/2018	Rice Flour	140.00	≤100(inorg)	Y
1/6/2018	Rice Flour	140.00	≤100(inorg)	Y
4/6/2018	Rice Flour	140.00	≤100(inorg)	Y
9/4/2019	Org. rice	132.30	≤200	Y
11/3/2017	Org.Cumin	130.20	≤1000	Y
2/15/2018	Rice Flour	130.00	≤100(inorg)	Y
2/5/2018	Rice Flour	130.00	≤100(inorg)	Y
2/8/2018	Rice Flour	130.00	≤100(inorg)	Y
1/5/2018	Rice Flour	122.30	≤100(inorg)	Y
1/5/2018	Rice Flour	120.80	≤100(inorg)	Y
2/8/2018	Rice Flour	120.00	≤100(inorg)	Y
1/18/2017	Org.Rice	110.00	≤200	Y
5/8/2018	Rice Flour	110.00	≤100(inorg)	Y
5/17/2017	Rice	110.00	≤200	Y
2/6/2017	Vitamin Mix	106.90	<3000	Y

The six Beech-Nut ingredients with the highest arsenic levels—Amylase, BAN 800, Alpha Amylase, and Sebamyl 100—are all enzymes that Beech-Nut adds to its products. BAN 800 is an enzyme that reportedly “[i]ncreases crumb softness” in baked goods.<sup>46</sup> Amylase is an

<sup>46</sup> Novozymes, *Meet Consumer Demands with Enzymes that Support Organic Labeling* (May 2018) (online at [www.novozymes.com/-/media/Project/Novozymes/Website/website/document-library/Advance-your-business/Baking/Baking-Product-Range-for-Organic-Production.pdf](http://www.novozymes.com/-/media/Project/Novozymes/Website/website/document-library/Advance-your-business/Baking/Baking-Product-Range-for-Organic-Production.pdf)).

enzyme that is “used in bread-making as an additive to improve the conversion of complex sugars into simple sugars that yeast are then able to feed on and produce alcohol and CO<sub>2</sub>.”<sup>47</sup>

**4. Gerber used 67 batches of rice flour that had more than 90 ppb inorganic arsenic.**

Gerber did not provide inorganic arsenic results for all of its ingredients. However, test results for conventional rice flour revealed that Gerber routinely used flour with over 90 ppb inorganic arsenic.<sup>48</sup> Gerber used five batches of rice flour that had 98 ppb inorganic arsenic, and 67 batches that contained more than 90 ppb.

***Gerber Products Company Test Results (Excerpted Entries)***<sup>49</sup>

Year	Ingredient	Total Arsenic (ppb)	Inorganic Arsenic (ppb)
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	105	98
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2018	Flour Rice Long Grain Tote NGM InfG Kshr	107	97
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96

<sup>47</sup> ChefSteps, *Amylase* (online at [www.chefsteps.com/ingredients/amylase](http://www.chefsteps.com/ingredients/amylase)) (accessed Jan. 26, 2021).

<sup>48</sup> Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf)).

<sup>49</sup> *Id.*

2019	Flour Rice Long Grain Tote NGM InfG Kshr	105	96
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	95	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	123	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2018	Flour Rice Long Grain Tote NGM InfG Kshr	124	95
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	94	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2017	Flour Rice Long Grain Tote NGM InfG Kshr	118	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
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2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	111	94
2018	Flour Rice Long Grain Tote NGM InfG Kshr	121	93
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	123	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	92	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2017	Flour Rice Long Grain Tote NGM InfG Kshr	108	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92

2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2018	Flour Rice Long Grain Tote NGM InfG Kshr	120	92
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91
2019	Flour Rice Long Grain Tote NGM InfG Kshr	138	91

## B. Lead

There is a growing consensus among health experts that lead levels in baby foods should not exceed 1 ppb. The American Academy for Pediatrics, the Environmental Defense Fund, and Consumer Reports have all, in some form, called for a 1 ppb level in food and drinks that babies and children consume.<sup>50</sup> Healthy Babies Bright Futures has called for a goal of no measurable amount of lead in baby food.<sup>51</sup>

There is no federal standard for lead in baby food. However, FDA has set a 5 ppb lead standard for bottled water, WHO has set 10 ppb lead as a provisional guideline for drinking water, and EPA has set an action level of 15 ppb for lead in drinking water. FDA has also set standards for lead in juice (50 ppb) and candy (100 ppb). The European Union has set the maximum lead level in infant formula to 20 ppb.<sup>52</sup>

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<sup>50</sup> American Academy of Pediatrics, *Prevention of Childhood Lead Toxicity* (May 5, 2016) (online at <https://pediatrics.aappublications.org/content/pediatrics/early/2016/06/16/peds.2016-1493.full.pdf>); Environmental Defense Fund, *Lead in Food: A Hidden Health Threat* (June 15, 2017) (online at [www.edf.org/sites/default/files/edf\\_lead\\_food\\_report\\_final.pdf](http://www.edf.org/sites/default/files/edf_lead_food_report_final.pdf)); Consumer Reports, *Consumer Reports Letter to FDA on Reducing Heavy Elements Like Arsenic, Lead, and Cadmium in Fruit Juices* (Jan. 30, 2019) (online at <https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/>).

<sup>51</sup> Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at [www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport\\_FULLREPORT\\_ENGLISH\\_R5b.pdf](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>52</sup> World Health Organization, *Lead in Drinking-Water* (2011) (online at [www.who.int/water\\_sanitation\\_health/dwq/chemicals/lead.pdf](http://www.who.int/water_sanitation_health/dwq/chemicals/lead.pdf)); Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at [www.epa.gov/dwreginfo/lead-and-copper-rule](http://www.epa.gov/dwreginfo/lead-and-copper-rule)) (accessed Jan. 26, 2021); European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

*Proposed and Existing Lead Standards*

Group or Agency	Standard
Environmental Defense Fund	1 ppb, especially for baby food
Consumer Reports	1 ppb in fruit juices
American Academy of Pediatrics (AAP)	1 ppb for water fountains in schools
FDA	5 ppb for bottled water
World Health Organization	10 ppb provisional guideline
EPA	15 ppb for drinking water (action level)
European Union (EU)	20 ppb for “infant formulae and follow-on formulae”
FDA	50 ppb for juice
	100 ppb for candy

The Subcommittee’s investigation has found that baby food manufacturers are selling baby food with higher levels of lead than what is allowed by existing standards for water, juice, and candy. Internal testing data from Gerber, Nurture, Beech-Nut, and Hain demonstrate that all four companies sold products or used ingredients with significant amounts of lead. Only Nurture routinely tested its finished product for lead. Hain, Beech-Nut, and Gerber did not test their finished products, only their ingredients. All companies, whether they test their final products or merely their ingredients, sold baby foods even when they or their ingredients contained unsafe levels of lead.

**1. Nurture (HappyBABY) sold finished baby food products after testing confirmed they contained as much as 641 ppb lead, over six times its already-dangerously-high internal standard.**

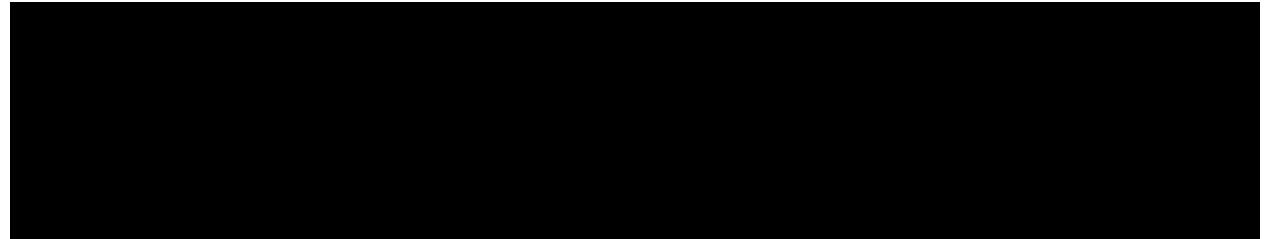
Nurture sold products that tested as high as 641 ppb lead—over six times higher than its internal limit of 100 ppb lead.<sup>53</sup> Nurture also sold five other products after they tested over 50 ppb lead.<sup>54</sup>

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<sup>53</sup> Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

<sup>54</sup> *Id.*

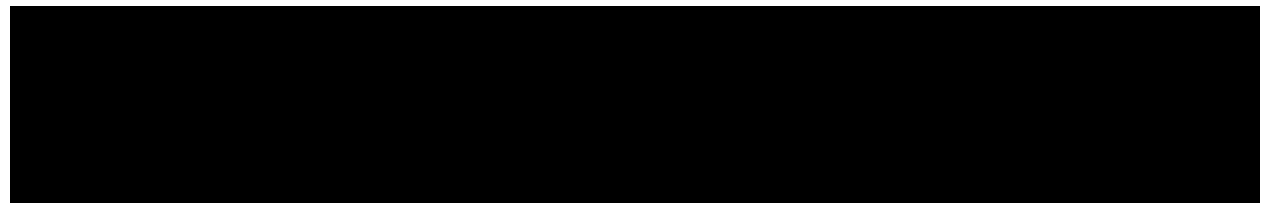


*Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*<sup>55</sup>

Of the 206 finished products that Nurture tested for lead, 16 products registered over 20 ppb lead—exceeding the lenient EU standard. And 39 products, or 18.9%, tested over 10 ppb lead.<sup>56</sup> It is not clear that even one of Nurture's baby food products registered at or below 1 ppb lead, which should be the upper limit for lead content according to the health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics.

2. **Beech-Nut used ingredients containing as much as 886.9 ppb lead; Beech-Nut routinely used ingredients with high lead content, including 483 ingredients that contained over 5 ppb lead, 89 ingredients that contained over 15 ppb lead, and 57 ingredients that contained over 20 ppb lead.**

Beech-Nut used ingredients in its baby foods that contained high lead levels. For instance, Beech-Nut used cinnamon that contained 886.9 ppb lead.<sup>57</sup>

*Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entry)*<sup>58</sup>

Beech-Nut tested and used 57 ingredients that contained over 20 ppb lead, the EU's lax standard for lead in infant formula. Beech-Nut accepted 89 ingredients that tested at or over 15 ppb lead, EPA's action level for drinking water, and 483 ingredients that tested at or over 5 ppb lead, FDA's standard for lead in bottled water.<sup>59</sup>

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<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

***Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)***<sup>60</sup>

Date	Commodity	Lead result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	Cinnamon	886.9	≤1000	Y
5/21/2018	Org. Cumin	644.9	≤1000	Y
8/11/2017	Org. Coriander	603.5	<1000	Y
10/11/2016	Oregano	570.4	<1000	Y
7/14/2017	Org. Cumin	231.2	≤1000	y
5/31/2017	Cinnamon	203.9	≤1000	Y
3/30/2017	Cumin	177.7	≤1000	Y
11/3/2017	Org. Cumin	167.7	≤1000	Y
12/5/2017	Org. Cinnamon	126.2	≤1000	Y
11/29/2017	Alpha Amylase	114.5	<300	Y
9/19/2018	Amylase	108.8	<300	Y
7/11/2017	Org. Lemon	102	≤160	Y
7/8/2019	Org. Cinnamon	100	≤1000	Y
7/12/2019	Org. Cinnamon	100	≤1000	Y
10/12/2017	Amylase	95.8	<300	Y
4/26/2018	Amylase	91	<300	Y
4/12/2017	Turmeric	76.3	≤1000	Y
8/27/2018	Sunflower Lecithin	71.6	≤100	Y
8/3/2017	Org. Lemon	63.7	≤160	Y

<sup>60</sup> *Id.*

4/11/2018	Org. Cinnamon	59	≤1000	Y
11/2/2018	S. Potato	55.3	≤15	Y
4/21/2017	Sunflower Lecithin	54.9	≤100	Y
8/15/2018	Quinoa Flour	51.6	<75	Y
11/2/2018	S. Potato	50.1	≤15	Y
10/25/2016	Lemon	47.5	≤160	Y
1/14/2019	Enzyme	47.3	<300	Y
5/31/2018	Prune Puree	41.5	≤40	Y - ER
11/6/2018	S. Potato	40.3	≤15	Y
9/29/2017	Org. Turmeric	39.3	≤1000	Y
9/13/2019	Org. Cinnamon	37.8	≤1000	Y
8/11/2017	Org. Cinnamon	36.7	≤1000	y
11/6/2018	S. Potato	35.2	≤15	Y
11/2/2018	S. Potato	34.9	≤15	Y
10/10/2018	Dehydrated Potato	32.4	<75	Y - ER
8/2/2018	Mango	32.3	≤20	Y
11/2/2018	S. Potato	31.8	≤15	Y
6/11/2018	Sunflower Lecithin	31.7	≤100	Y
8/6/2018	Prune	31.1	≤40	
8/20/2019	Sebamyl 100	30.6	<300	Y
3/19/2018	Org. Prune	30	≤40	Y
9/20/2016	Apricot	28	≤20	Y - ER
2/13/2019	Org. Prune	27.9	≤40	Y - ER

6/7/2019	Enzyme	26.3	<300	Y
6/19/2018	Org. Quinoa Flour	25.3	<75	Y - ER
2/6/2017	Vitamin Mix	24.6	<10	Y
9/28/2017	Org. Quinoa Seeds	24.2	<75	Y
9/28/2017	Org. Quinoa Seeds	24.2	<75	Y
2/1/2019	Blueberry	22.7	<25	Y
11/6/2018	S. Potato	22	≤15	Y
3/18/2019	Org. Pears	21.7	<10	
6/14/2019	Sunflower Lecithin	21	≤100	Y
3/20/2018	Carrots	20	<25	Y - ER
3/20/2018	Carrots	20	<25	Y - ER
3/19/2018	Carrots	20	<25	Y - ER
3/19/2018	Carrots	20	<25	Y - ER
3/16/2017	Sunflower Lecithin	20	≤100	Y
3/1/2019	Org. Cinnamon	20	≤1000	Y

**3. Hain (Earth's Best Organic) used ingredients containing as much as 352 ppb lead; Hain consistently used baby food ingredients with high lead content, including 88 ingredients that tested over 20 ppb lead and six ingredients that tested over 200 ppb lead.**

Hain used an ingredient called vitamin pre-mix in its baby food that contained as much as 352 ppb lead.<sup>61</sup>

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<sup>61</sup> Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

***Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entry)***<sup>62</sup>

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/C	As Purchased	100	223	100	352

Hain used six ingredients that tested above 200 ppb lead. Hain used 88 ingredients with lead levels at or over 20 ppb—the EU's standard for lead in infant formula. Hain accepted 115 ingredients that registered at or over 15 ppb—EPA's action level for drinking water. And at least 27% of Hain ingredients tested at or over 5 ppb lead, FDA's standard for lead in bottled water. None of the test results showed an ingredient below 1 ppb lead, which should be the upper limit for lead content according to the health experts at Consumer Reports, the Environmental Defense Fund, and the American Academy of Pediatrics.

***Hain's Raw Material Pre-Shipment Test Data History (Excepted Entries for Ingredients Above 200 ppb Lead)***<sup>63</sup>

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Cadmium Spec Limit (ppb)	Cadmium Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/C	As Purchased	100	223	100	60.5	100	352
Jan/19/2018	Grain Millers	471138	Org Whole Wheat Fine Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	160	100	250
Dec/28/2017	Grain Millers	471011	Org Quick Oats	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	<100	100	230
Dec/27/2017	Grain Millers	55300	Org Barley Flour	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	120	100	<100	100	230
Nov/3/2017	Starwest Botanicals	40500	Org Cinnamon Powder	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	110	100	200	100	230
Jan/22/2018	Jewel Date	14300	Org Date Paste	Accepted	Calculated Levels on consumed basis	Deibel	As consumed	100	<100	100	190	100	220

**4. Gerber used ingredients that tested as high as 48 ppb lead; and routinely accepted ingredients containing over 20 ppb lead.**

Gerber produced limited lead testing results. The results for its sweet potatoes and juices demonstrated its willingness to use ingredients that contained dangerous lead levels. Gerber used an ingredient, conventional sweet potatoes, with 48 ppb lead. Gerber also used twelve other batches of sweet potato that tested over 20 ppb for lead, the EU's lenient upper standard.<sup>64</sup>

<sup>62</sup> *Id.*

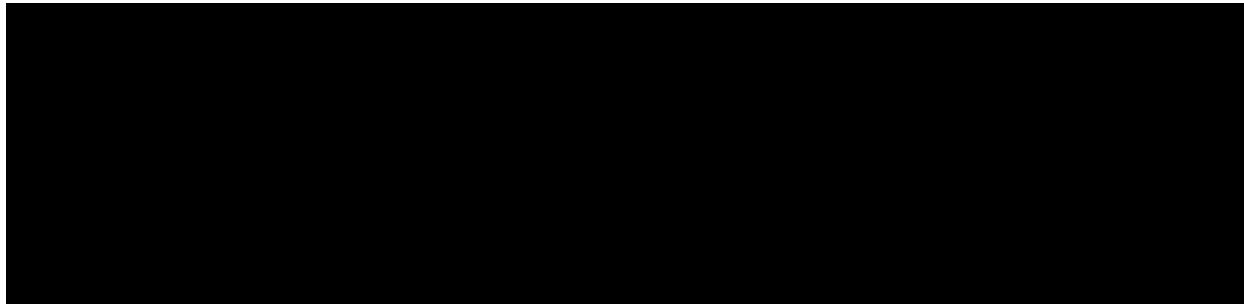
<sup>63</sup> *Id.*

<sup>64</sup> Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf)).

*Gerber Products Company Test Results (Excerpted Entries)*<sup>65</sup>

Year	Ingredient	Lead Level (ppb)
2017	Conventional	48
2017	Organic	35
2017	Organic	34
2017	Organic	34
2018	Conventional	34
2019	Conventional	34
2019	Conventional	34
2018	Organic	25
2019	Organic	25
2018	Organic	22
2018	Organic	22
2018	Organic	21
2019	Conventional	21

The average amount of lead in Gerber’s tested juice concentrates was 11.2 ppb—more than FDA’s limit for lead in bottled water. Over 83% of the juice concentrates tested showed greater than 1 ppb lead, which is Consumer Reports’ recommended limit for fruit juices.

*Gerber Products Company Test Results (Excerpted Entries)*<sup>66</sup>


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<sup>65</sup> *Id.*

<sup>66</sup> *Id.*

### C. Cadmium

Outside the context of baby food, some regulation has taken action against cadmium. For example, EPA has a limit of 5 ppb in drinking water, and FDA has set a limit of 5 ppb in bottled water.<sup>67</sup> These standards approach WHO's 3 ppb limit for cadmium in drinking water.<sup>68</sup>

Groups like Healthy Babies Bright Futures have set a goal of no measurable amount of cadmium in baby food.<sup>69</sup> Consumer Reports has called for a limit of 1 ppb cadmium in fruit juices.<sup>70</sup> And the EU has set a limit ranging from 5–20 ppb cadmium for infant formula.

The Subcommittee found that baby food manufacturers sold many products with much higher cadmium content.

#### *Proposed and Existing Cadmium Standards*

Group or Agency	Standard
Consumer Reports	1 ppb in all fruit juices
World Health Organization	3 ppb for drinking water
EPA	5 ppb for drinking water
FDA	5 ppb for drinking water
European Union (EU)	5-20 ppb for infant formulae

#### 1. **Beech-Nut used ingredients in its baby food containing up to 344.55 ppb cadmium; 105 Beech-Nut ingredients tested over 20 ppb cadmium.**

Beech-Nut used twenty ingredients registering over 100 ppb cadmium, including cinnamon containing 344.5 ppb cadmium.<sup>71</sup> That is more than 17 times higher than the EU's lax

<sup>67</sup> Environmental Protection Agency, *Ground Water and Drinking Water* (online at [www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations](http://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations)) (accessed Jan. 26, 2021); 21 C.F.R. § 165 (2019) (online at [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110)).

<sup>68</sup> World Health Organization, *Cadmium in Drinking-Water* (2011) (online at [www.who.int/water\\_sanitation\\_health/water-quality/guidelines/chemicals/cadmium.pdf?ua=1](http://www.who.int/water_sanitation_health/water-quality/guidelines/chemicals/cadmium.pdf?ua=1)).

<sup>69</sup> Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at [www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport\\_FULLREPORT\\_ENGLISH\\_R5b.pdf](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>70</sup> Consumer Reports, *Consumer Reports Letter To FDA On Reducing Heavy Elements Like Arsenic, Lead, and Cadmium in Fruit Juices* (Jan. 30, 2019) (online at <https://advocacy.consumerreports.org/research/consumer-reports-letter-to-fda-on-reducing-heavy-elements-like-arsenic-lead-and-cadmium-in-fruit-juices/>); European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

<sup>71</sup> Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

upper limit on cadmium in baby food. At least 105 ingredients that Beech-Nut tested and used in baby foods registered at or over 20 ppb cadmium—the EU’s lax infant formula upper limit.<sup>72</sup>

***Beech-Nut’s Raw Materials Heavy Metal Testing (Excerpted Entries)***<sup>73</sup>

Date	Commodity	Cadmium Result (ppb)	Spec.	Acceptance (Y/N)
10/19/2016	Cinnamon	344.50	≤1000	Y
4/11/2018	Org. Cinnamon	225.10	≤1000	Y
5/31/2017	Cinnamon	194.30	≤1000	Y
6/8/2018	Org. Garlic	186.00	≤1000	Y
8/11/2017	Org. Cinnamon	178.20	≤1000	y
10/11/2016	Oregano	176.50	<1000	Y
12/5/2017	Org. Cinnamon	163.40	≤1000	Y
11/29/2017	Dehydrated Potato	148.40	<90	Y - ER
10/10/2018	Dehydrated Potato	146.00	<90	Y
10/10/2018	Dehydrated Potato	143.50	<90	Y - ER
7/10/2019	Spinach Puree	143.00	<180	Y
7/2/2018	Fresh Spinach	142.30	<180	Y
7/8/2019	Org. Cinnamon	140.00	≤1000	Y
7/12/2019	Org. Cinnamon	140.00	≤1000	Y
3/1/2019	Org. Cinnamon	120.00	≤1000	Y
11/29/2017	Dehydrated Potato	119.60	<90	Y - ER
9/13/2019	Org. Cinnamon	117.30	≤1000	Y
7/15/2019	Spinach	117.00	<180	Y
7/15/2019	Spinach	101.00	<180	Y
7/15/2019	Spinach	101.00	<180	Y

**2. Hain (Earth’s Best Organic) used ingredients in its baby food containing up to 260 ppb cadmium; 102 Hain ingredients tested over 20 ppb cadmium.**

Hain used 14 ingredients that contained more than 100 ppb cadmium, including barley flour that registered at 260 ppb cadmium.<sup>74</sup> That is thirteen times the EU’s lax upper limit on cadmium in baby food. Hain tested and used 102 ingredients that registered at or above 20 ppb cadmium—the EU’s lax upper limit.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

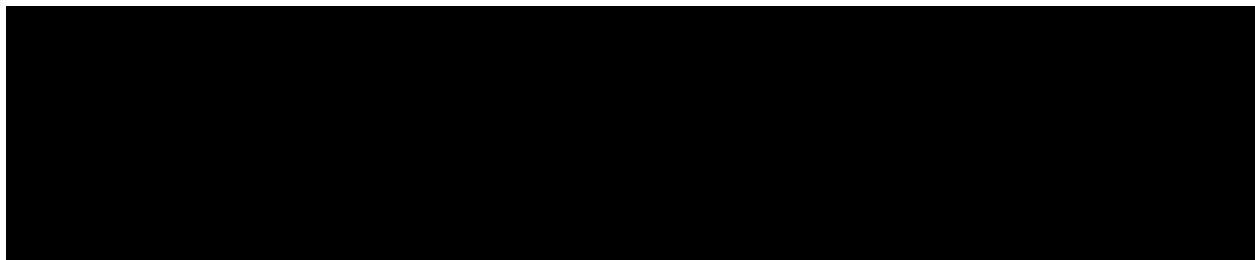


*Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)*<sup>75</sup>

Lab Results Date	Products Description	Status	Cadmium Spec. limit (ppb)	Cadmium Result (ppb)
Jan/19/2018	Org Barley Flour	Accepted	100	260
Jan/22/2018	IQF Org Chopped Broccoli	Accepted	100	250
Jan/23/2018	Org Date Paste	Accepted	100	220
Nov/3/2017	Org Cinnamon Powder	Accepted	100	200
Aug/21/2017	Org Brown Flax Milled	Accepted	100	190
Jan/22/2018	Org Date Paste	Accepted	100	190
Jan/18/2018	Org Yellow Papaya Puree	Accepted	100	170
Jan/19/2018	Org Whole Wheat Fine Flour	Accepted	100	160
Aug/17/2017	Org Red Lentils	Accepted	100	130
Jan/15/2018	Org Oat Flakes	Accepted	100	130
Jun/13/2018	Org Brown Flax Milled	Accepted	100	121
Jan/12/2018	Org Barley Flour	Accepted	100	110
Jun/25/2018	Org Oat Flour	Accepted	100	102
Feb/19/2019	Org Cinnamon Powder	Deviation Approved	100	102

**3. Sixty-five percent of Nurture (HappyBABY) finished baby food products contained more than 5 ppb cadmium, the EPA's limit for drinking water.**

Nurture sold multi-grain cereal with 49 ppb cadmium. Nurture sold another 125 products that tested over 5 ppb, which is the EPA's limit for drinking water.<sup>76</sup>

*Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*<sup>77</sup>

<sup>75</sup> *Id.*

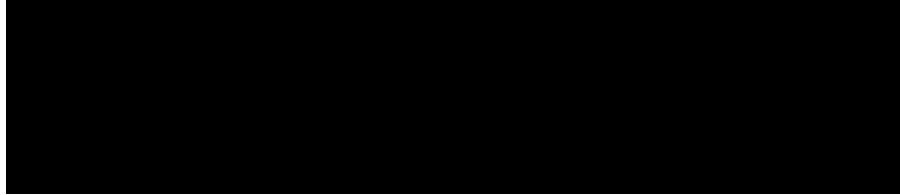
<sup>76</sup> Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

<sup>77</sup> *Id.*

**4. Gerber used carrots containing as much as 87 ppb cadmium; 75% of Gerber's carrots contain cadmium in excess of 5 ppb.**

Gerber does not test all its ingredients for cadmium. Of those it does test, it accepts ingredients with high levels of cadmium. Gerber used multiple batches of carrots containing as much as 87 ppb cadmium, and 75% of the carrots Gerber used had more than 5 ppb cadmium—the EPA's drinking water standard.<sup>78</sup>

***Gerber Products Company Test Results (Excerpted Entries)*<sup>79</sup>**



**D. Mercury**

Outside the context of baby food, some regulation has taken action against mercury. EPA, for example, has capped mercury in drinking water at 2 ppb.<sup>80</sup> Consumer advocates urge even stricter standards for baby food. For example, Health Babies Bright Futures has called for a goal of no measurable amount of mercury in baby food.<sup>81</sup>

**1. Nurture (HappyBABY) sold finished baby food products containing as much as 10 ppb mercury.**

Nurture sold a finished baby food product that contained 10 ppb mercury, and two others that contained 9.8 and 7.3 ppb. A level of 10 ppb is five times more than the EPA's 2 ppb standard for drinking water. In total, Nurture sold 56 products that contained over 2 ppb mercury.<sup>82</sup>

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<sup>78</sup> Gerber, *Gerber Products Company Test Results* (Dec. 9, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf)).

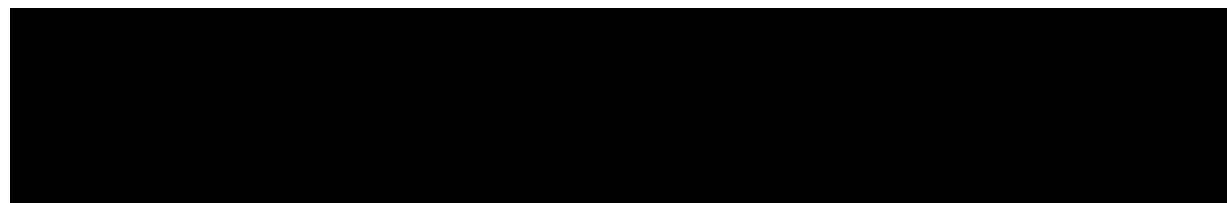
<sup>79</sup> *Id.*

<sup>80</sup> Environmental Protection Agency, *Ground Water and Drinking Water* (online at [www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations](http://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations)) (accessed Jan. 26, 2021).

<sup>81</sup> Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at [www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport\\_FULLREPORT\\_ENGLISH\\_R5b.pdf](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>82</sup> Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

*Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)*<sup>83</sup>



**2. Beech-Nut and Hain (Earth's Best Organic) did not even test for mercury in baby food; Gerber barely tests for it.**

From the documents produced to this Subcommittee, it appears that neither Beech-Nut nor Hain tests their ingredients or their finished products for mercury.

Gerber only tests certain ingredients for mercury. Of the test results they presented to the Subcommittee, they only tested carrots, sweet potatoes, and lemon juice concentrate.

**III. INDUSTRY SELF-REGULATION FAILS TO PROTECT CONSUMERS: NURTURE, BEECH-NUT, HAIN, AND GERBER SET THEIR OWN DANGEROUSLY HIGH INTERNAL STANDARDS FOR TOXIC HEAVY METAL LEVELS AND ROUTINELY IGNORED THEM TO SELL PRODUCTS WITH HIGHER HEAVY METAL LEVELS.**

Baby food manufacturers are free to set their own internal standards for toxic heavy metal content of their products. They have set those standards at dangerously high levels and have often sold foods that exceed even those levels.

**A. Nurture (HappyBABY) sets high internal standards and regularly exceeds them. Nurture admits that its toxic heavy metal testing is not for safety—it sells all products tested, regardless of its toxic heavy metal content. FDA has finalized only one standard—100 ppb inorganic arsenic in infant rice cereal—Nurture has ignored it, setting its internal standard for that product at 115 ppb.**

Nurture created internal standards but did not follow them. Nurture describes these standards as “goal thresholds” that “are not used to make product disposition decisions and are not a pre-condition to product release.”<sup>84</sup> Instead, its testing regime is limited to monitoring the supply chain. Nurture’s thresholds are not actually used to prevent products that contain high levels of toxic heavy metals from being sold.<sup>85</sup>

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<sup>83</sup> *Id.*

<sup>84</sup> Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

<sup>85</sup> *Id.*

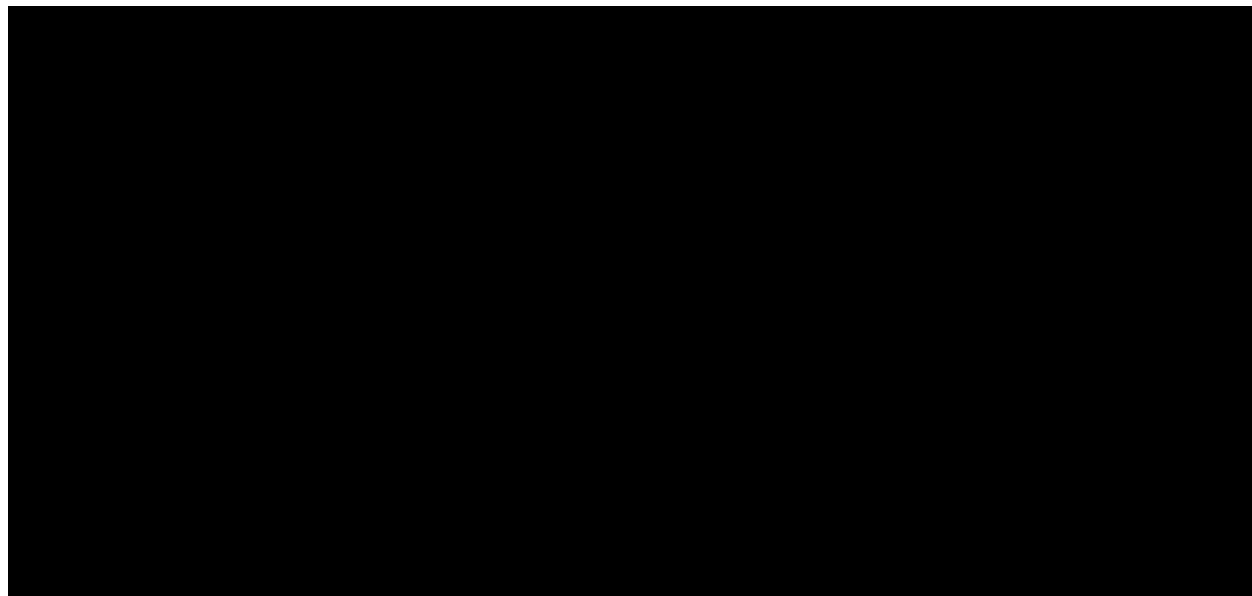
Nurture does not even claim to be testing for safety—it made clear in its letter response to this Subcommittee that all products will be sold regardless of testing result: **“our heavy metal testing is performed as part of our monitoring program and not as a condition of product release, all of the products that were tested were sold into commerce.”**<sup>86</sup>

Nurture sells the products it tests, regardless of their toxic heavy metal content. In total, Nurture tested 113 final products and sold every product tested, regardless of how much inorganic arsenic or lead the product contained, and regardless of whether those metals exceeded its own internal standards.

As a result of this policy of not testing for safety, Nurture released products containing as much as 641 ppb lead and 180 ppb inorganic arsenic.<sup>87</sup>

Nurture sold 29 products that were above its internal arsenic limit of 100 ppb, including Apple & Broccoli Puffs that contained 180 ppb inorganic arsenic. Nurture’s standards “are not used to make product disposition decisions and are not a pre-condition to product release.” Instead, their testing regime is limited to monitoring the supply chain.<sup>88</sup>

***Nurture’s Heavy Metal Test Results for Baby Food Products (Excerpted Entries)***<sup>89</sup>




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<sup>86</sup> *Id.*

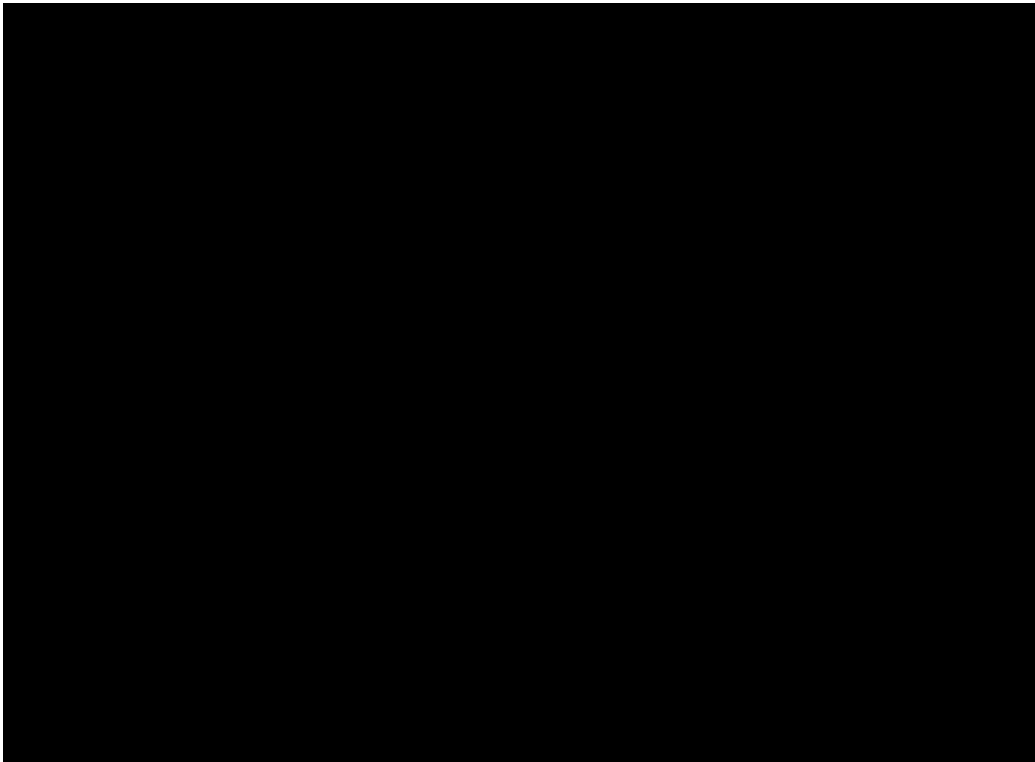
<sup>87</sup> Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

<sup>88</sup> Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

<sup>89</sup> Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

Further, Nurture appears to have misled the Subcommittee about its testing standards. As seen from Nurture's goal thresholds pictured below, Nurture conveyed to the Subcommittee that after January of 2019, it had a goal threshold of 50 ppb for lead in all of its baby food products—infant formula, cereals, and wet foods.<sup>90</sup> However, in the test results that Nurture provided to this Subcommittee, it was still using 100 ppb as an internal guideline after January 2019.

This image is from Nurture's December 18, 2019, response to the Subcommittee, stating that after January of 2019, its lead threshold was 50 ppb in all baby food products:<sup>91</sup>



However, the chart below appears to show that after the date Nurture claims to have moved to a 50 ppb lead standard—January 2019—Nurture was still using a “Goal Threshold” of 100 ppb for 53 baby food products. The fact that Nurture appears to have continued using a higher standard up to nine months after it claimed to the Subcommittee to have lowered the threshold casts serious doubt on Nurture's candor in this matter.

***Nurture's Heavy Metal Test Results for Baby Food Products (Excerpted Entries)***<sup>92</sup>

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<sup>90</sup> Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

<sup>91</sup> *Id.*

<sup>92</sup> Nurture, *Heavy Metal Test Results for Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

Product Name	Parameter	Goal Threshold	Result	Unit	Date of Test Report
Blueberry Beet Rice Cakes	Lead	100	<4.0	ppb	10/14/19
Stage 3 Root Vegetable and Turkey	Lead	100	<4.0	ppb	10/11/19
Apple & Broccoli Puffs	Lead	100	5.8	ppb	10/10/19
Apple Cinnamon Oat Jar	Lead	100	<4.0	ppb	10/09/19
Apple Spinach Jar	Lead	100	<4.0	ppb	10/09/19
Kale & Spinach Puffs	Lead	100	9.7	ppb	10/09/19
Apple Mango Beet	Lead	100	<4.0	ppb	08/22/19
Pear Prune Jar	Lead	100	<4.0	ppb	08/22/19
Apple Spinach Pea & Kiwi	Lead	100	43	ppb	08/22/19
Pea Spinach Teether	Lead	100	18	ppb	08/16/19
Strawberry Yogis	Lead	100	<4.0	ppb	08/13/19
Sweet Potato & Carrot Puffs	Lead	100	7.7	ppb	07/25/19
Banana & Pumpkin Puffs	Lead	100	6.2	ppb	07/25/19
Apples Blueberries & Oats	Lead	100	<4.0	ppb	07/24/19
CC Oats & Quinoa Cereal	Lead	100	<4.0	ppb	07/24/19
Green Beans Jar	Lead	100	<4.0	ppb	07/24/19
Pears Mangoes & Spinach	Lead	100	<4.0	ppb	07/24/19
Carrots	Lead	100	<4.0	ppb	07/20/19
Pea Spinach Teether	Lead	100	23	ppb	07/11/19
Apple & Broccoli Puffs	Lead	100	11	ppb	07/11/19
Kale & Spinach Puffs	Lead	100	11	ppb	07/11/19
Mangoes	Lead	100	<4.0	ppb	07/03/19
Sweet Potatoes Jar	Lead	100	<4.0	ppb	07/03/19
CC Oats & Quinoa Cereal	Lead	100	<4.0	ppb	07/02/19
Harvest Vegetables & Chicken	Lead	100	<4.0	ppb	07/02/19
Apple Rice Cakes	Lead	100	7.2	ppb	07/02/19
Blueberry Purple Carrot Greek Yogis	Lead	100	4.3	ppb	07/02/19
Apple & Broccoli Puffs	Lead	100	9.9	ppb	05/30/19
Strawberry & Beet Puffs	Lead	100	10	ppb	05/22/19
Apples & Spinach	Lead	100	<4.0	ppb	05/15/19
Clearly Crafted Apple Guava Beet	Lead	100	<4.0	ppb	05/10/19
Sweet Potato Jar	Lead	100	<4.0	ppb	05/10/19
Banana & Pumpkin Puffs	Lead	100	13	ppb	04/24/19
Sweet Potato & Carrot Puffs	Lead	100	7.7	ppb	04/24/19
Apple Pumpkin Carrots	Lead	100	<4.0	ppb	04/12/19
Pea Spinach Teether	Lead	100	23	ppb	04/12/19
Multi-Grain Cereal Canister	Lead	100	5.2	ppb	04/12/19
Carrots	Lead	100	<4.0	ppb	04/11/19
Sweet Potato Jar	Lead	100	<4.0	ppb	04/11/19
Apple Spinach Pea & Kiwi	Lead	100	34	ppb	03/29/19
Strawberry & Beet Puffs	Lead	100	7.8	ppb	03/21/19

Banana & Pumpkin Puffs	Lead	100	5.5	ppb	03/21/19
CC Oatmeal Cereal	Lead	100	<4.0	ppb	03/18/19
Carrots & Peas	Lead	100	<4.0	ppb	03/13/19
CC Prunes	Lead	100	<4.0	ppb	03/13/19
Pears & Kale Jar	Lead	100	<4.0	ppb	03/13/19
Vegetable & Beef Medley	Lead	100	<4.0	ppb	03/07/19
Banana Sweet Potato Teether	Lead	100	12	ppb	02/19/19
Banana & Pumpkin Puffs	Lead	100	11	ppb	02/19/19
Blueberry Purple Carrot Teether	Lead	100	10	ppb	02/19/19
Mangoes	Lead	100	<4.0	ppb	02/13/19
Apple Mango Beet	Lead	100	<4.0	ppb	02/12/19
Strawberry Banana Greek Yogis	Lead	100	<4.0	ppb	02/12/19

Nurture has also ignored the only final standard that FDA has set. FDA set a 100 ppb inorganic arsenic limit for infant rice cereal. Rather than comply with that limit, Nurture set its internal standards 15% higher, at 115 ppb inorganic arsenic.<sup>93</sup>

*Excerpt of December 18, 2019, Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi*<sup>94</sup>



**B. Beech-Nut set internal arsenic and cadmium standards at 3,000 ppb in dangerous additives, such as vitamin mix, and 5,000 ppb lead for certain ingredients like BAN 800. These standards are the highest of any responding manufacturer.**

Beech-Nut has set an internal specification limit (listed in the chart below as “spec.”) of 3,000 ppb inorganic arsenic for certain ingredients, including vitamin mix.<sup>95</sup> As a result of

<sup>93</sup> Letter from Nurture, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 18, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/10.pdf>).

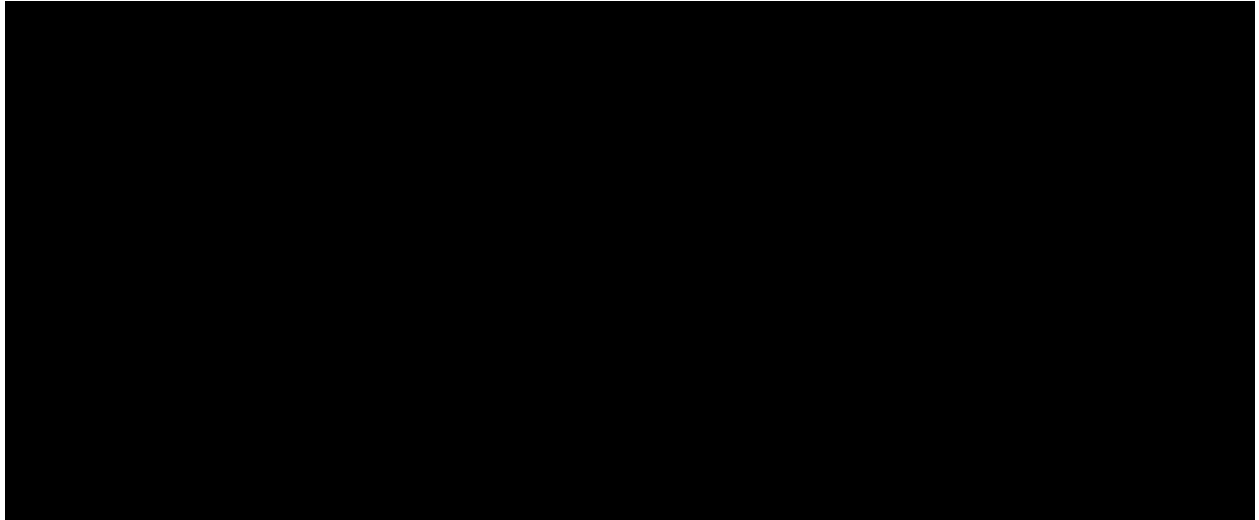
<sup>94</sup> *Id.*

<sup>95</sup> Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).



adopting this high internal standard, Beech-Nut has used ingredients containing 710.9, 465.2, and 401.4 ppb arsenic.<sup>96</sup> Beech-Nut also set internal guidelines of 3,000 ppb for cadmium and 5,000 ppb for lead for certain ingredients.<sup>97</sup> These far surpass any existing regulatory standard in existence and toxic heavy metal levels for any other baby food manufacturer that responded to the Subcommittee's inquiry.

***Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)***<sup>98</sup>



Beech-Nut sold eleven products that surpassed its own internal cadmium limits. By doing so, Beech-Nut accepted dehydrated potato containing 119.6, 143.5, and 148.4 ppb cadmium, far surpassing its own internal limit of 90 ppb for that ingredient.<sup>99</sup>

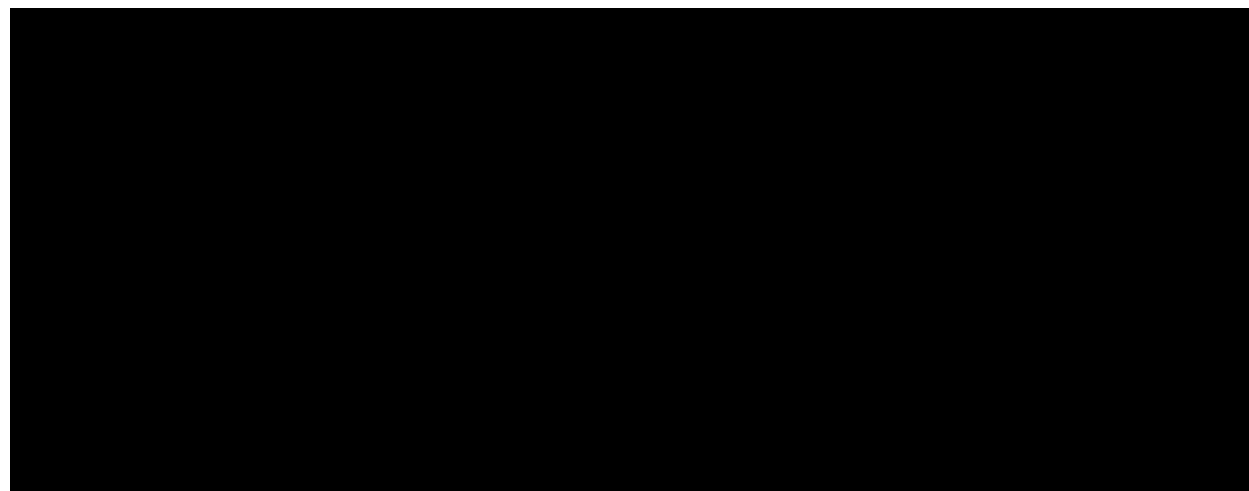
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<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

***Beech-Nut's Raw Materials Heavy Metal Testing (Excerpted Entries)***<sup>100</sup>

Beech-Nut's explanation of why it accepted products over its own internal limits was that it did so "rarely" and the ingredients were "generally restricted to a 20% variance of BNN's allowable limits...."<sup>101</sup> However, as the cadmium examples show, Beech-Nut accepted certain ingredients in spite of their own testing results which showed that they contained over 20% more cadmium than their already-high internal limit. Beech-Nut's internal limit for cadmium in dehydrated potato appears to be 90 ppb. A 20% variance would permit Beech-Nut to accept dehydrated potato containing up to 108 ppb cadmium. Nevertheless, Beech-Nut accepted three shipments of dehydrated potato containing cadmium in excess of its 20% variance allowance.<sup>102</sup> Beech-Nut did not offer any explanation.

**C. Hain (Earth's Best Organic) set an internal standard of 200 ppb for arsenic, lead, and cadmium in some of its ingredients. Hain justified deviations above its ingredient testing standards based on "theoretical calculations," even after Hain admitted to FDA that its testing underestimated final product toxic heavy metal levels.**

Hain set an internal standard of 200 ppb arsenic for 12 ingredients, most of which were different kinds of flours. By setting this high internal standard, Hain justified accepting wheat flour and rice that contained 200 and 150 ppb arsenic.<sup>103</sup>

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<sup>100</sup> *Id.*

<sup>101</sup> Letter from the President and Chief Executive Officer of Beech-Nut Nutrition Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 6, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf)).

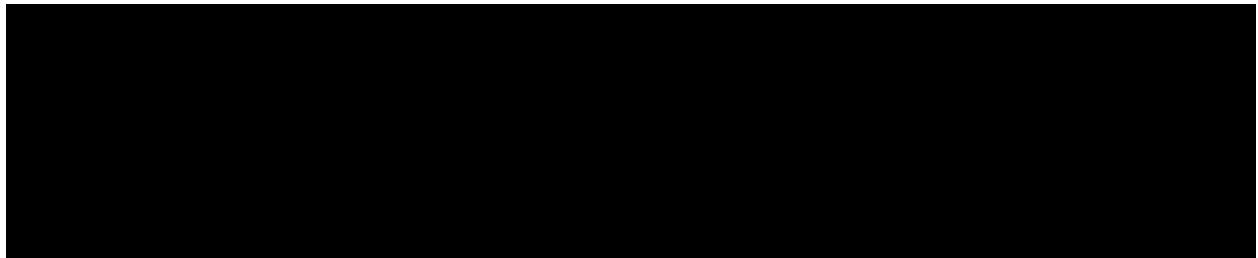
<sup>102</sup> Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

<sup>103</sup> Hain, *Raw Material Pre-Shipment Test Data History* (Dec. 11, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

*Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)*<sup>104</sup>

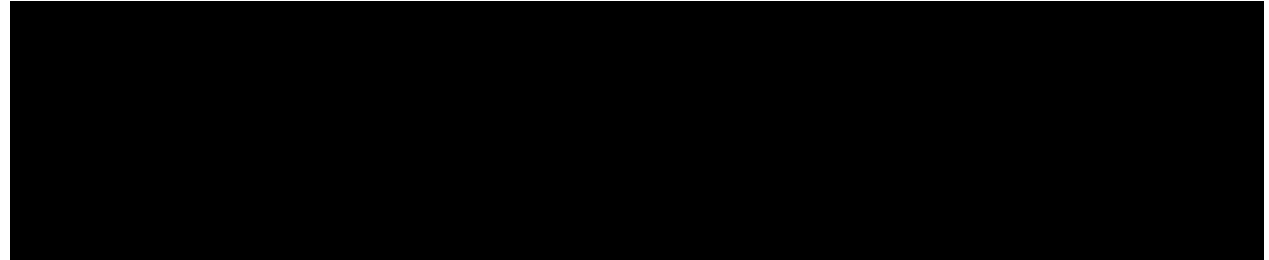
Lab Results Date	Product Description	Status	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)
Aug/3/2017	Org Kamut Flour	Accepted	200	<100
Aug/3/2017	Org Spelt Flour	Accepted	200	<100
Jul/6/2017	Org Yellow Split Pea Powder	Accepted	200	<100
Jul/5/2017	Org Quinoa Flour	Accepted	200	<100
May/26/2017	Org Soft White Wheat Flour	Accepted	200	<100
Aug/1/2017	Org Fiber Oat	Accepted	200	<100
Sep/25/2017	Org Quinoa Flour	Accepted	200	<100
Sep/12/2017	Org Spelt Flour	Accepted	200	<100
Aug/4/2017	Org Spelt Flour	Accepted	200	<100
Jul/19/2017	Org Green Lentil Flour	Accepted	200	<100
Sep/29/2017	Org Soft White Wheat Flour	Accepted	200	200
Jul/13/2017	Medium Grain Whole Rice	Accepted	200	150

Similarly, Hain set an internal limit of 200 ppb for lead in five ingredients—forty times higher than FDA's guidance for bottled water. By doing so, Hain justified accepting lentil flour with 110 ppb lead and quinoa flour with 120 ppb lead. These surpass every existing regulatory standard for lead.<sup>105</sup>

*Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)*<sup>106</sup><sup>104</sup> *Id.*<sup>105</sup> *Id.*<sup>106</sup> *Id.*

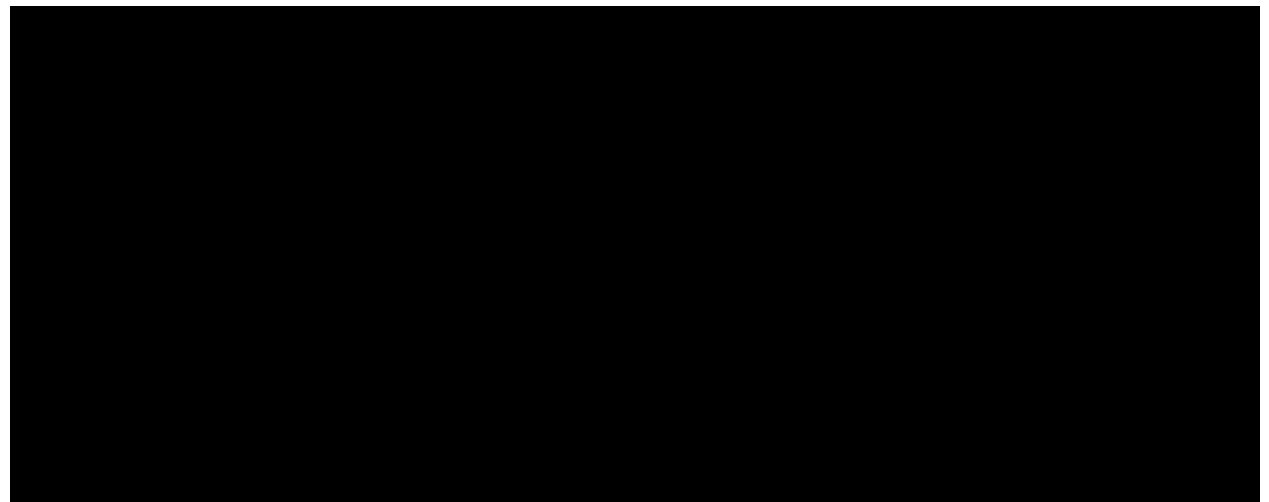
Hain used four products that surpassed its internal toxic heavy metal limits. For example, it accepted cinnamon that contained 102 ppb cadmium, vitamin pre-mix that had 223 ppb arsenic and 353 ppb lead, and two rice flours that had 134 and 309 ppb arsenic.<sup>107</sup>

*Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entries)*<sup>108</sup>



Hain justified these variations by claiming that the “theoretical” final goods will not surpass its internal limits. For example, Hain became aware that the vitamin pre-mix contained 223 ppb arsenic and 352 ppb lead.<sup>109</sup>

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*<sup>110</sup>



Despite having dangerously high levels of toxic heavy metals, Hain approved the use of this vitamin pre-mix based on a “theoretical” calculation of toxic heavy metals in the final good.<sup>111</sup>

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<sup>107</sup> *Id.*

<sup>108</sup> *Id.*

<sup>109</sup> Hain, *Deviation Report, Vitamin Premix* (Nov. 26, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/11\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/11_Redacted.pdf)).

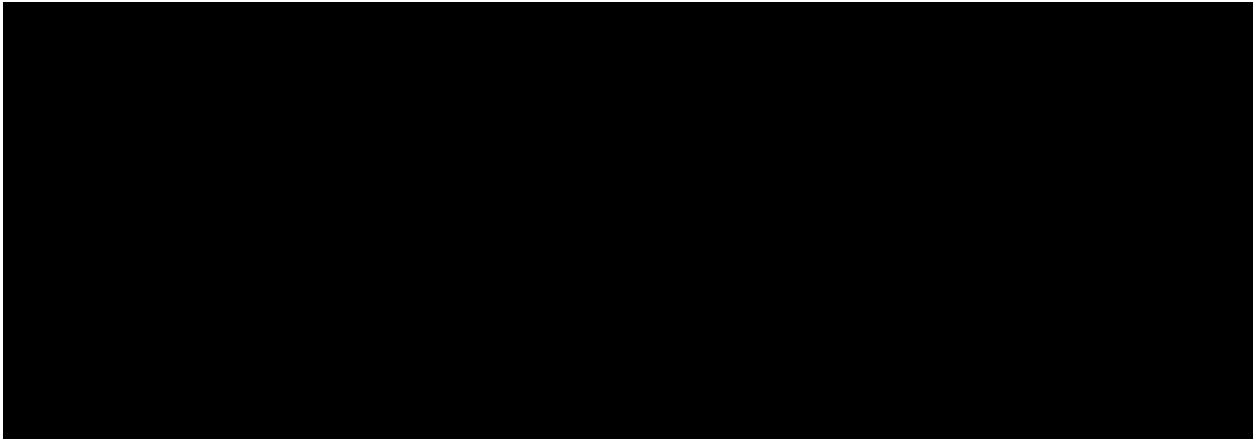
<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*<sup>112</sup>

QUALITY & FOOD SAFETY REVIEW		
Reviewed Date	11/26/2019	Select one: <input checked="" type="radio"/> Approved <input type="radio"/> Rejected <input type="radio"/> Revisions Requested
Reviewed By	[REDACTED]	
Comments	Vitamin premix is used at 2.08% in the rice cereal finished good C90001. Upon theoretical calculations including the 10% variation, the arsenic and lead levels in the finished product are below 100 ppb. Attached calculations.	

To calculate the estimated quantity of lead and arsenic in the finished good, Hain considered the percentage of rice flour and vitamin pre-mix in the finished goods, and their projected amounts of arsenic and lead. Ultimately, Hain predicted that the finished good would have roughly 85 ppb arsenic and 25 ppb lead.<sup>113</sup>

*Hain Deviation Report, Vitamin Premix (Nov. 26, 2019)*<sup>114</sup>

However, it is not clear that Hain ever tested the finished good. Hain appears to have used this vitamin pre-mix with dangerously high levels of toxic heavy metals without ever confirming the finished good was actually safe to consume.

Hain made this decision four months *after* it had made a secret presentation to FDA admitting that heavily tainted vitamin premix caused dangerous levels of arsenic in its finished

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<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Id.*

products, which initially went undetected because Hain did not test its finished products.<sup>115</sup> Hain made no effort to correct the problem. *Note: Full discussion of Hain's secret presentation to FDA appears in Section V., Parts D. and E., below.*

#### IV. WALMART, SPROUT ORGANIC FOODS, AND CAMPBELL REFUSED TO COOPERATE WITH THE SUBCOMMITTEE'S INVESTIGATION

Nurture, Beech-Nut, Hain, and Gerber cooperated with the Subcommittee's investigation, despite the fact that doing so exposed their reckless disregard for the health of babies. With that in mind, the Subcommittee questions why Walmart (Parent's Choice), Sprout Organic Foods, and Campbell (Plum Organics) would refuse to comply with the investigation. None of them produced testing results or specific testing standards and Sprout never even responded to the Subcommittee's repeated inquiries. The Subcommittee is greatly concerned that these companies might be obscuring the presence of even higher levels of toxic heavy metals in their baby food products than their competitors' products.

##### A. Walmart (Parent's Choice Brand)

Walmart refused to produce any documents showing its internal testing policies, its testing results, or how Walmart treats ingredients and/or products that surpass any internal standards.

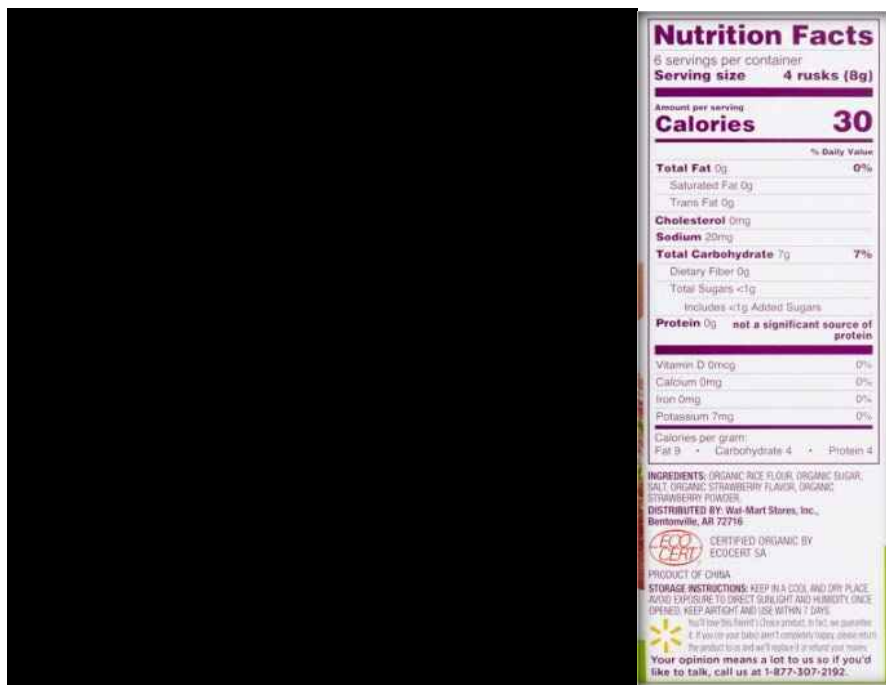
Walmart's evasion is concerning, as even limited independent testing has revealed the presence of toxic heavy metals in its baby food.

##### *Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?*<sup>116</sup>

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Parent's Choice (Walmart)	Little Hearts Strawberry Yogurt Cereal Snack - Stage 3, 9+ months	Snack - other	56.1	—	5.2	26.1	0.941	Charlottesville, VA	Walmart
Parent's Choice (Walmart)	Organic Strawberry Rice Rusks - Stage 2, 6+ months	Snack - teething biscuits & rice rusks/cakes	108	66	26.9	2.4	2.05	Charlottesville, VA	Walmart

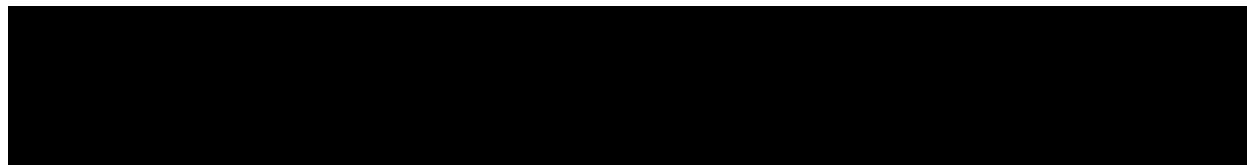
<sup>115</sup> Hain, PowerPoint Presentation to Food and Drug Administration: *FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

<sup>116</sup> Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at [www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport\\_FULLREPORT\\_ENGLISH\\_R5b.pdf](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

***Walmart (Parent's Choice) Baby Food that Tested High in Toxic Heavy Metals***<sup>117</sup>**B. Campbell (Plum Organics Brand)**

Campbell refused to produce its testing standards and specific testing results to the Subcommittee. Campbell has hidden its policies and the actual level of toxic heavy metals in its products.

Instead of producing any substantive information, Campbell provided a spreadsheet self-declaring that every one of its products “meets criteria.”<sup>118</sup> Campbell declined to state what those criteria are.

***Campbell's Product Heavy Metal Test Results (Excerpted Entries)***<sup>119</sup>

<sup>117</sup> Walmart, *Parent's Choice Organic Strawberry Rice Rusks* (online at [www.walmart.com/ip/Parent-s-Choice-Organic-Baby-Rusks-Strawberry-Flavored/171533478](http://www.walmart.com/ip/Parent-s-Choice-Organic-Baby-Rusks-Strawberry-Flavored/171533478)) (accessed on Jan. 26, 2021).

<sup>118</sup> Campbell, *Product Heavy Metal Test Results* (Dec. 11, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/12.pdf>).

<sup>119</sup> *Id.*



Campbell's testing summary hides more than it reveals, since it does not show the levels of heavy metals that the testing found or the levels of heavy metals that would "meet criteria."

The Subcommittee was disturbed that, for mercury, which is a powerful neurotoxin, Campbell notes with asterisks that it has no criterion whatsoever, stating: "No specific threshold established because no high-risk ingredients are used."<sup>120</sup> However, despite Campbell having no mercury threshold, Campbell still marked every food as "meets criteria" for mercury.<sup>121</sup> This misleading framing—of meeting criteria that do not exist—raises questions about what Campbell's other thresholds actually are, and whether they exist.

Campbell's evasion is concerning, as even limited independent testing has revealed the presence of toxic heavy metals in its baby food.

***Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?***<sup>122</sup>

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Plum Organics	Mighty Morning Bar - Blueberry Lemon - Tots: 15 months & up	Snack - other	40 *	39	3.4	24.3	<0.137	Cincinnati, OH	Kroger
Plum Organics	Little Teethers Organic Multigrain Teething Wafers - Banana with Pumpkin - Baby Crawler	Snack - teething biscuits & rice rusks/cakes	49.9	—	1.4 *	6.3	0.726	Columbia, SC	Publix

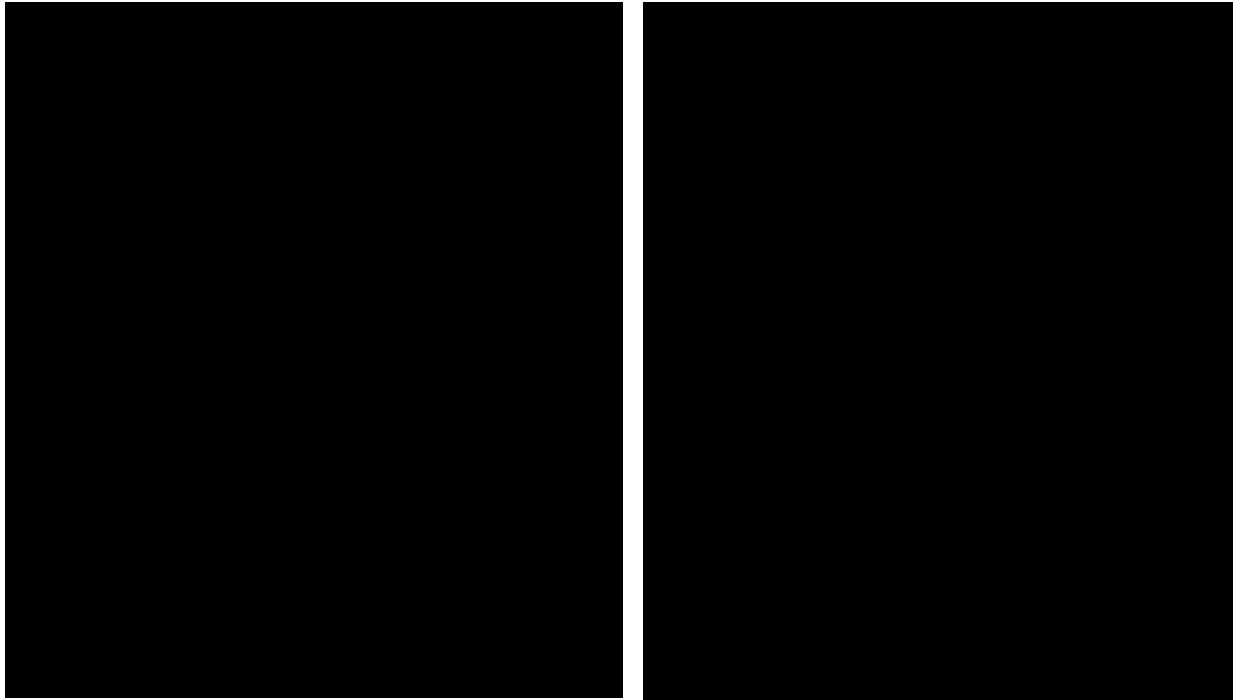
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<sup>120</sup> *Id.*

<sup>121</sup> *Id.*

<sup>122</sup> Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at [www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport\\_FULLREPORT\\_ENGLISH\\_R5b.pdf](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

*Plum Organics' Foods That Tested High in Toxic Heavy Metals*<sup>123</sup>



**C. Sprout Organic Foods**

Sprout Organic Foods did not respond to the Subcommittee at all. Despite numerous emails to executives and its general information email address, as well as numerous attempts to reach the Sprout central office by telephone, Sprout never responded or made contact with the Subcommittee.

Sprout Organic Foods was acquired by North Castle Partners, a Greenwich, Connecticut private equity firm, in 2015. North Castle Partners also owns such well-known brands as Curves International/Jenny Craig, Palladio Beauty Group, Mineral Fusion, Red Door Spas, Performance Bicycles, Octane Fitness, Ibex Outdoor Clothing, and Doctor's Best.<sup>124</sup>

Whether due to evasion or negligence, Sprout's failure to respond raises serious concerns about the presence of toxic heavy metals in its baby foods, as even limited independent testing has revealed the presence of toxic heavy metals in its products.

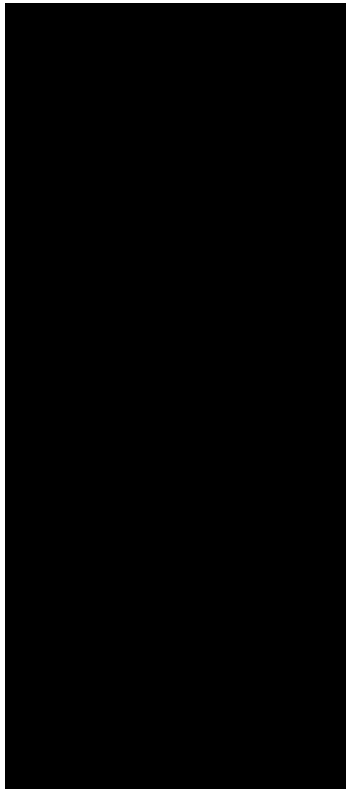
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<sup>123</sup> Plum Organics, *Little Teethers, Banana with Pumpkin* (online at [www.plumorganics.com/products/banana-with-pumpkin-wafers/](http://www.plumorganics.com/products/banana-with-pumpkin-wafers/)) (accessed Jan. 26, 2021); Plum Organics, *Mighty Morning Bar, Blueberry Lemon* (online at [www.plumorganics.com/products/blueberry-lemon-bar/](http://www.plumorganics.com/products/blueberry-lemon-bar/)) (accessed Jan. 26, 2021).

<sup>124</sup> North Castle Partners, *Press Release: North Castle Partners Invests in Sprout Organic Foods, Inc.* (June 29, 2015) (online at [www.northcastlepartners.com/wp-content/uploads/2016/01/North-Castle\\_Sprout-Press-Release.pdf](http://www.northcastlepartners.com/wp-content/uploads/2016/01/North-Castle_Sprout-Press-Release.pdf)).

***Data from Healthy Babies Bright Futures Report: What's in My Baby's Food?***<sup>125</sup>

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Sprout	Organic Quinoa Puffs Baby Cereal Snack - Apple Kale	Snack - puffs, contains rice	107	47	39.3	41.5	1.31	Washington, DC	amazon.com

***Sprout Organic Food That Tested High in Toxic Heavy Metals***<sup>126</sup>

**V. FDA HAS FAILED TO CONFRONT THE RISKS OF TOXIC HEAVY METALS IN BABY FOOD. THE TRUMP ADMINISTRATION IGNORED A SECRET INDUSTRY PRESENTATION ABOUT HIGHER AMOUNTS OF TOXIC HEAVY METALS IN FINISHED BABY FOODS.**

Despite the well-known risks of harm to babies from toxic heavy metals, FDA has not taken adequate steps to decrease their presence in baby foods. FDA has not issued thresholds for the vast majority of toxic heavy metals in baby foods and does not require warning labels on any baby food products. In the summer of 2019, FDA received a secret presentation from a baby

<sup>125</sup> Healthy Babies Bright Futures, *What's in My Baby's Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies' IQ, Including Arsenic and Lead* (Oct. 2019) (online at [www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport\\_FULLREPORT\\_ENGLISH\\_R5b.pdf](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>126</sup> Sprout Organic Foods, *Quinoa Puffs, Apple Kale* (online at [www.sproutorganicfoods.com/babies/6-months-and-up/plant-power-puffs/apple-kale-plant-power-puffs](http://www.sproutorganicfoods.com/babies/6-months-and-up/plant-power-puffs/apple-kale-plant-power-puffs)) (accessed Jan. 26, 2021).

food manufacturer that revealed that the commercial process of preparing finished baby foods increases their levels of toxic heavy metals. For that manufacturer, Hain (HappyBABY), the process increased inorganic arsenic levels between 28% and 93%. Yet, FDA took no apparent action.

In May 2017, FDA established the Toxic Elements Working Group with the goal of reducing exposure to toxic elements in food, cosmetics, and dietary supplements. FDA claims that the Toxic Elements Working Group is focusing on metals “because high levels of exposure to those metals are likely to have the most significant impact on public health,” and “can be especially harmful to children because of concerns about effects on their neurological development.”<sup>127</sup> But the working group has not resulted in new or stronger regulations to protect babies from toxic heavy metals in their food.

#### A. Mercury and Cadmium

FDA has acknowledged the dangers of mercury. Mercury has “no established health benefit” and has been “shown to lead to illness, impairment, and in high doses, death.”<sup>128</sup> FDA has acknowledged the added risk to babies and children, noting that it is: “paying special attention to children because their smaller body sizes and metabolism may make them more susceptible to the harmful effects of these metals,” including mercury.<sup>129</sup>

Despite these statements, FDA has taken no action to limit mercury in baby food. Instead, FDA has only set mercury standards for wheat, and fish, shellfish, and crustaceans, and they are high—1,000 ppb.<sup>130</sup> There are no FDA protections for mercury in baby food.

The lack of FDA action on mercury standards stands in contrast to other regulators. The EPA, for example, set a limit of 2 ppb mercury in drinking water, even after taking into account the cost of attainment for industry.<sup>131</sup>

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<sup>127</sup> Food and Drug Administration, *Metals and Your Food* (online at [www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food](http://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food)) (accessed Jan. 26, 2021); Food and Drug Administration, *What FDA Is Doing to Protect Consumers from Toxic Metals in Foods* (Apr. 20, 2018) (online at [www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods](http://www.fda.gov/food/conversations-experts-food-topics/what-fda-doing-protect-consumers-toxic-metals-foods)).

<sup>128</sup> Food and Drug Administration, *Metals and Your Food* (online at [www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food](http://www.fda.gov/food/chemicals-metals-pesticides-food/metals-and-your-food)) (accessed Jan. 26, 2021).

<sup>129</sup> *Id.*

<sup>130</sup> Food and Drug Administration, *Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed* (Aug. 2000) (online at [www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-levels-poisonous-or-deleterious-substances-human-food-and-animal-feed)).

<sup>131</sup> Environmental Protection Agency, *Ground Water and Drinking Water* (online at [www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations](http://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations)) (accessed Jan. 26, 2021).

Similarly, FDA has taken no action on cadmium in baby food. FDA has issued only one guideline for cadmium, and that is a limit of 5 ppb for bottled water.<sup>132</sup> The EU has instituted a limit of 10-15 ppb for infant formula.<sup>133</sup>

## B. Lead

FDA acknowledges that there is “no identified safe blood lead level” and that lead is especially dangerous to children:

Lead is especially harmful to vulnerable populations, including infants, young children, pregnant women and their fetuses, and others with chronic health conditions. High levels of lead exposure can seriously harm children’s health and development, specifically the brain and nervous system. Neurological effects from high levels of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time.<sup>134</sup>

FDA has taken action on bottled water, limiting lead to 5 ppb.<sup>135</sup> FDA has also taken steps toward regulating lead content in products for older children. FDA has released guidance recommending a maximum lead level of 100 ppb in candy likely to be consumed by children, and 50 ppb in some juices.<sup>136</sup> It is not sound logic to say that water is unsafe to drink if it contains over 5 ppb lead, but candy and fruit juice can be ten and twenty times higher than that limit.

Unfortunately, it appears that FDA designed these limits to be protective of industry. In its “Supporting Document for Recommended Maximum Level for Lead in Candy,” FDA repeatedly emphasizes achievability by industry, as opposed to safety for children:

- “FDA believes that sugar-based candy products *can be made* with lead levels below” [100 ppb].”
- “We believe *that if milk chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed* [100 ppb] lead.”
- “We believe that, *if dark chocolate manufacturers source their raw materials appropriately, lead levels in their finished products will not exceed* [100 ppb].”

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<sup>132</sup> 21 C.F.R. § 165 (2019) (online at [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=165.110)).

<sup>133</sup> European Union, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* (Dec. 19, 2006) (online at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1881-20150521>).

<sup>134</sup> Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at [www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements](http://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

- “[E]ven for high-chili-content candy and powdered snack mix products, *we believe that candy with appropriately sourced ingredients will not exceed* [100 ppb] lead.”
- “We believe that *if manufacturers source salt to minimize lead levels, finished, high-salt- content powdered snack mix products will not exceed* [100 ppb] lead.”<sup>137</sup>

But FDA has failed to regulate lead levels in baby foods. Manufacturers are free to set their own limits. Hain, for example, used internal soft limits of 100 and 200 ppb lead for the majority of its ingredients.

FDA *has* created what it calls an Interim Reference Level (IRL) for lead, but this standard does not apply to manufacturers and is unhelpful for parents purchasing baby food. An Interim Reference Level is what FDA calls a calculation of “the maximum daily intake for lead from food.”<sup>138</sup> Above this limit, a person or baby’s blood level would reach a “point of concern.” FDA’s current IRL is 3 µg per day for children. This standard, though perhaps helpful to FDA in researching and evaluating how lead affects our nation’s children, is unworkable for parents. For this standard to be useful to a parent, they would need to know:

- what a µg is (it stands for a microgram);
- how much lead is in each product they are serving their baby;
- how much lead their child is exposed to through tap water; and
- how much lead is in their local environment, such as through lead-based paints.

Obtaining this information is currently impossible for parents because baby food manufacturers do not publicly provide information on the amount of lead in their products. Given the information gaps parents face, it would be most appropriate for FDA to promulgate clear rules for baby food manufacturers that limit the amount of lead in baby food.

### C. Arsenic

In the context of arsenic in baby food, there are only two FDA regulations for specific products—an unenforceable draft guidance issued in July 2013, but never finalized, recommending an action level of 10 ppb for inorganic arsenic in single-strength (ready to drink) apple juice, and an August 2020 final guidance, setting an action level for inorganic arsenic in infant rice cereals at 100 ppb.<sup>139</sup>

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<sup>137</sup> Food and Drug Administration, *Supporting Document for Recommended Maximum Level for Lead in Candy Likely to Be Consumed Frequently by Small Children* (Nov. 2006) (online at [www.fda.gov/food/metals-and-your-food/supporting-document-recommended-maximum-level-lead-candy-likely-be-consumed-frequently-small](http://www.fda.gov/food/metals-and-your-food/supporting-document-recommended-maximum-level-lead-candy-likely-be-consumed-frequently-small)) (emphasis added).

<sup>138</sup> Food and Drug Administration, *Lead in Food, Foodwares, and Dietary Supplements* (online at [www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements](http://www.fda.gov/food/metals-and-your-food/lead-food-foodwares-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>139</sup> Food and Drug Administration, *Draft Guidance for Industry: Action Level for Arsenic in Apple Juice* (July 2013) (online at [www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-level-arsenic-apple-juice](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-level-arsenic-apple-juice)); Food and Drug Administration, *Guidance for Industry: Action Level for*

The first problem with these standards is that they cover only a small sliver of the foods babies eat.

The second problem is that they are far too lax to be protective of babies. There is no established safe level of inorganic arsenic consumption for babies. Arsenic exposure has a “significant negative effect on neurodevelopment.”<sup>140</sup> FDA acknowledged that “Low-to-moderate levels of inorganic arsenic appear to be associated with adverse health effects during childhood.”<sup>141</sup> Children exposed to water with an arsenic concentration of just 5 ppb “showed significant reductions in Full Scale, Working Memory, Perceptual Reasoning and Verbal Comprehension scores.”<sup>142</sup> This suggests that 5 ppb may be an important threshold, or that the threshold of safety may fall far below that.

Healthy Babies Bright Futures has called for a goal of no measurable amount of inorganic arsenic in baby food.<sup>143</sup> Consumer Reports suggests that the level of inorganic arsenic should be set as low as 3 ppb for water and fruit juices.<sup>144</sup>

FDA has already set inorganic arsenic levels at 10 ppb for bottled water.<sup>145</sup> EPA has similarly set a 10 ppb inorganic arsenic cap on water, as have the European Union and the World Health Organization.<sup>146</sup>

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*Inorganic Arsenic in Rice Cereals for Infants* (Aug. 2020) (online at [www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-action-level-inorganic-arsenic-rice-cereals-infants)).

<sup>140</sup> Miguel Rodríguez-Barranco et al., *Association of Arsenic, Cadmium and Manganese Exposure with Neurodevelopment and Behavioural Disorders in Children: A Systematic Review and Meta-Analysis* (Apr. 9, 2013) (online at [www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub](http://www.sciencedirect.com/science/article/abs/pii/S0048969713003409?via%3Dihub)).

<sup>141</sup> Food and Drug Administration, *Arsenic in Rice and Rice Products Risk Assessment Report* (Mar. 2016) (online at [www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf](http://www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf)).

<sup>142</sup> Gail A. Wasserman et al., *A Cross-Sectional Study of Well Water Arsenic and Child IQ in Maine Schoolchildren* (Apr. 1, 2014) (online at <https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-13-23>).

<sup>143</sup> Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95 Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic and Lead* (Oct. 2019) (online at [www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport\\_FULLREPORT\\_ENGLISH\\_R5b.pdf](http://www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf)).

<sup>144</sup> Consumer Reports, *Arsenic in Some Bottled Water Brands at Unsafe Levels, Consumer Reports Says* (June 28, 2019) (online at [www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/](http://www.consumerreports.org/water-quality/arsenic-in-some-bottled-water-brands-at-unsafe-levels/)); Consumer Reports, *Arsenic and Lead Are in Your Fruit Juice: What You Need to Know* (Jan. 30, 2019) (online at [www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/](http://www.consumerreports.org/food-safety/arsenic-and-lead-are-in-your-fruit-juice-what-you-need-to-know/)).

<sup>145</sup> Food and Drug Administration, *Arsenic in Food and Dietary Supplements* (online at [www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements](http://www.fda.gov/food/metals-and-your-food/arsenic-food-and-dietary-supplements)) (accessed Jan. 26, 2021).

<sup>146</sup> Environmental Protection Agency, *Drinking Water Requirements for States and Public Water Systems* (online at [www.epa.gov/dwreginfo/chemical-contaminant-rules](http://www.epa.gov/dwreginfo/chemical-contaminant-rules)) (accessed Jan. 26, 2021); The European Food Information Council, *Arsenic (Q&A)* (online at [www.eufic.org/en/food-safety/article/arsenic-qa](http://www.eufic.org/en/food-safety/article/arsenic-qa)) (accessed Jan. 26, 2021); World Health Organization, *Arsenic* (Feb. 15, 2018) (online at [www.who.int/news-room/fact-sheets/detail/arsenic](http://www.who.int/news-room/fact-sheets/detail/arsenic)).



FDA is fully aware of the dangers that inorganic arsenic presents to young children, stating that:

There is growing evidence ... that exposure to inorganic arsenic during...infancy...may increase the risk of adverse health effects, including impaired development during...childhood and neurodevelopmental toxicity in infants and young children, and that these adverse effects may persist later in life .... [C]hildren may likewise be particularly susceptible to neurotoxic effects of inorganic arsenic, e.g., as manifested in intelligence test results in children .... Also, children three years and younger have the highest exposure to inorganic arsenic because they have 2-3-fold higher intakes of food on a per body mass basis as compared to adults. Therefore, a child's daily exposure to contaminants in food, such as inorganic arsenic in rice, could potentially be much higher than that of adults.<sup>147</sup>

Yet, in the one category of baby food for which FDA has finalized a standard—infant rice cereal—it set the maximum inorganic arsenic content at the dangerous level of 100 ppb.

Why did FDA set its level so high? Because in developing the limit, FDA was focused on the level of inorganic arsenic that would cause cancer. FDA disregarded the risk of neurological damage, which happens at a much lower level. In its 2016 Risk Assessment Report, FDA was able to quantify the risk of lung and bladder cancer that inorganic arsenic presents. It was not able to quantify the risks of neurological development for infants.<sup>148</sup> As a result, the 100 ppb limit is too high to adequately protect infants and children from the effects of inorganic arsenic.

The third problem is that FDA's piecemeal approach of setting different inorganic arsenic standards for different products is logically unsound. There can be only one safe level for inorganic arsenic in the foods that babies consume. All finished baby food products should accord with this safe level.

Aside from these guidance documents for infant rice cereal and apple juice, FDA does not regulate toxic heavy metals in other baby food products.

One example of how this approach is failing is with FDA's decision to release draft guidance for apple juice, but not any other fruits juices. Based on the testing results the Subcommittee reviewed, baby food companies routinely exceed this draft limit of 10 ppb in other types of commonly consumed juices. Gerber, for example, used grape juice concentrate registering at 39 ppb inorganic arsenic. But because it was grape juice, as opposed to apple

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<sup>147</sup> Food and Drug Administration, *Supporting Document For Action Level For Inorganic Arsenic In Rice Cereals For Infants* (Aug. 2020) (online at [www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction](http://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction)).

<sup>148</sup> Food and Drug Administration, *Arsenic in Rice and Rice Products Risk Assessment Report* (Mar. 2016) (online at [www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf](http://www.fda.gov/files/food/published/Arsenic-in-Rice-and-Rice-Products-Risk-Assessment-Report-PDF.pdf)).

juice—which, from a safety perspective, is a distinction without a difference—Gerber incorporated in its products juice concentrate with high arsenic levels.

The fourth problem with FDA’s piecemeal approach is that it appears designed to be protective of baby food manufacturers. In developing the infant rice cereal limit of 100 ppb, FDA considered an “achievability assessment.” The achievability assessment considered “manufacturers’ ability to achieve hypothetical maximum limits for inorganic arsenic in infant rice cereals....”<sup>149</sup> FDA considered samples taken from three time periods: 2011-2013, 2014, and 2018. As shown below, over time, the number of samples that tested under 100 ppb inorganic arsenic increased from 36% to 76% of the total number of samples. FDA noted that this increase meant “alternate sources of rice are available to enable infant rice cereal manufacturers to supply the market and meet the” 100 ppb level.<sup>150</sup> In short, FDA’s standard reflects manufacturers’ ease of compliance, rather than babies’ safety.

If it is not possible, or it is exceedingly costly, to source ingredients like rice that achieve a safe level, then baby food manufacturers should find substitutes for those ingredients. Our nation’s children should not bear lifelong health burdens because of a manufacturer’s preference for tainted ingredients.

**D. The Trump Administration Ignored A Secret Industry Presentation About Higher Risks Of Toxic Heavy Metals In Baby Foods.**

On August 1, 2019, the Trump administration received a secret industry presentation that disclosed higher risks of toxic heavy metals in finished baby food products. Hain (Earth’s Best Organic) revealed the finding in a presentation to FDA entitled “FDA Testing Result Investigation.”<sup>151</sup>

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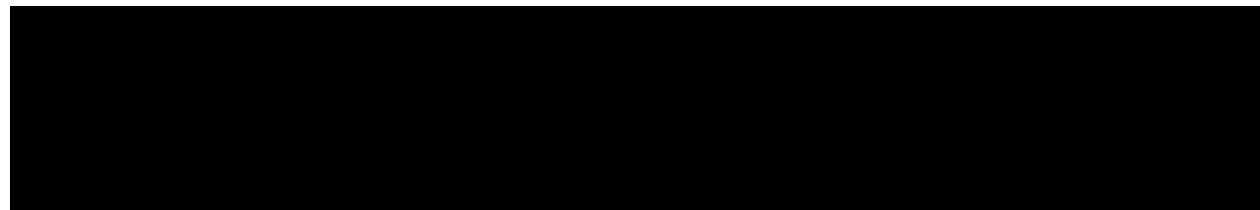
<sup>149</sup> Food and Drug Administration, *Supporting Document for Action Level for Inorganic Arsenic in Rice Cereals for Infants* (Aug. 2020) (online at [www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction](https://www.fda.gov/food/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations/supporting-document-action-level-inorganic-arsenic-rice-cereals-infants#introduction)).

<sup>150</sup> *Id.*

<sup>151</sup> Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).



Hain revealed that half (10 of 21) of the finished rice products that Hain tested contained 100 ppb or more of inorganic arsenic—exceeding FDA’s standard for infant rice cereal. One product contained almost 30% more, registering at 129 ppb inorganic arsenic.



Hain’s average level of inorganic arsenic in its finished rice foods was 97.62 ppb, which nearly matches FDA’s dangerously high 100 ppb level for inorganic arsenic for infant rice cereal.

Hain claims that it “revised its internal policies and testing standards to conform to FDA’s non-binding recommendations.”<sup>152</sup> In 2016, FDA instituted draft guidance (which is now final) for inorganic arsenic in infant rice cereal at the dangerously high level of 100 ppb. However, Hain has not consistently abided by those limits.

FDA also learned that Hain’s policy to test ingredients underrepresented the levels of toxic heavy metals in its finished baby foods. Hain’s finished products contained between 28% and 93% more inorganic arsenic than Hain estimated they would based on Hain’s ingredient

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<sup>152</sup> Letter from Kelly B. Kramer, Counsel for The Hain Celestial Group, Inc. to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 11, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/9\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/9_Redacted.pdf)).

testing method.<sup>153</sup> Hain found higher levels of arsenic in *all* finished foods tested for this FDA presentation than were reflected in tests of individual raw ingredients. This revelation means that every single finished good containing brown rice had more arsenic than the company's estimates, which were based on testing the raw ingredients.

After seeing these results, FDA was put on notice that finished baby foods pose an even higher risk to babies than reflected in company tests of the raw ingredients that go into those finished products.

***Final Product Data Compared to Raw Ingredient Data, From Hain's Presentation to FDA***<sup>154</sup>

FDA Data					Estimate % Avg FG Increase from Avg Raw	Track & Trace Data					
FDA Sample Number	Best By Date	Lot number	FDA FG Inorganic Arsenic (ppb)	Avg FG Result		Packaging Date	WIP Batch	Rice Flour Lot #s	Type of Arsenic Test	Raw Material Results (ppb)	Avg Raw Result
1017814	3/2/19	BN A 0636	54	80.3	41%	9/8/17	199987	B160004661	Total Arsenic	54	56.3
1038929		BN C 1139	83					B160004870	Total Arsenic	58	
1039633		BN F 1648	64				B160004759	Total Arsenic	57		
							B160004659	Total Arsenic	54		
						197594	B160004870	Total Arsenic	58		
							B160004759	Total Arsenic	57		
1039750	3/8/19	BN E	74	74.0	29%	9/14/17	200408	B160004871	Total Arsenic	60	57.3
								B160004870	Total Arsenic	58	
								B160004661	Total Arsenic	54	
1041752	3/20/19	BN G	52	96.0	57%	9/26/17	200651	B160005149	Total Arsenic	65	61.3
1037933		BN E 1536	67								
1041751	3/21/19	BN B 0832	108			9/27/17		B160004873	Total Arsenic	58	
1038677		BN B 0932	118					B160005157	Total Arsenic	62	
1026932		BN D 1248	97					B160004871	Total Arsenic	60	
										B160005148	
1044380	4/11/19	BN C	100	100.0	69%	10/18/17	201873	B160004872	Total Arsenic	55	59.0
								B160005152	Total Arsenic	61	
								B160005305	Total Arsenic	65	
1024309	4/27/19	BN I 2216	129	129.0	93%	11/3/17	204146	B160005306	Total Arsenic	76	67.0
								B160005512	Total Arsenic	62	
								B160005152	Total Arsenic	61	
1024210	6/6/19	BN I 2241	94	101.0	61%	12/13/17	206697	B160005515	Total Arsenic	63	62.7
947103		BN I 2339	115								
1013927	6/7/19	BN E 1540	52			12/14/17		B160005513	Total Arsenic	60	
1026516		BN H 2123	104								
1074288	6/8/19	BNE 1406	105			12/15/17					
1035738	6/13/19	BN I 0000	86			12/20/17		B160005150	Total Arsenic	65	
1047511	6/27/19	BN C 1142	100	100.0	56%	1/3/18	208226	B160006190	Inorganic Arsenic	73	64.0
								B160005581	Total Arsenic	55	
1063061	7/19/19	BN J	115	115.0	43%	1/25/18	208594	B160006189	Inorganic Arsenic	81	80.5
								B160006191	Inorganic Arsenic	80	
1027437	8/18/19	BN A 0703	97	97.0	28%	2/24/18	210374	B160006265	Inorganic Arsenic	77	75.7
								B160006263	Inorganic Arsenic	74	
								B160006260	Inorganic Arsenic	76	
784399	11/23/19	BN K 0305	108	108.0	31%	6/1/18	215305	B160007235	Inorganic Arsenic	66	82.5
								B160006755	Inorganic Arsenic	99	

Hain admitted to FDA in its presentation that "Brown Rice Flour testing results do not appear to be correlated to finished good results data."<sup>155</sup> They are not correlated because the finished goods can contain as much as double the amount of arsenic as the raw ingredients.

<sup>153</sup> Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

What can account for this increase in inorganic arsenic from the time the ingredients are tested to the time the products are finished? Hain conveyed to FDA that the cause of the increase was Hain's use of a dangerous additive, stating: "Preliminary investigation indicates Vitamin/Mineral Pre-Mix may be a major contributing factor." Although this additive may only make up roughly 2% of the final good, Hain suggested it was still responsible for the spike in the levels of inorganic arsenic in the finished baby food.<sup>156</sup>

Hain's finding accords with the Subcommittee's own. In the test results we reviewed, Hain used vitamin pre-mix that contained 223 ppb arsenic.<sup>157</sup> This ingredient also contained 352 ppb lead, a matter not even addressed in the FDA presentation.

***Hain's Raw Material Pre-Shipment Test Data History (Excerpted Entry)***<sup>158</sup>

Lab Results Date	Vendor Name	Item Number	Product Description	Status	Comments on Status	Lab	Spec Based On	Arsenic Spec Limit (ppb)	Arsenic Result (ppb)	Lead Spec Limit (ppb)	Lead Result (ppb)
Nov/26/2019	Wright Enrichment	5316067	Vitamin Pre Mix	Deviation Approved	Accepted on deviation 20190236	Eurofins/Covance	As Purchased	100	223	100	352

Therefore, naturally occurring toxic heavy metals may not be the only problem causing dangerous levels of toxic heavy metals in baby foods; rather, baby food producers like Hain are adding ingredients that have high levels of toxic heavy metals into their products, such as vitamin/mineral pre-mix.

FDA did not appear to take any unplanned actions on behalf of babies' safety after it received Hain's presentation. FDA did finalize a previously planned guidance, setting a limit of 100 ppb inorganic arsenic in infant rice cereal. But it did not initiate regulation of additives like Hain's vitamin/mineral pre-mix. Moreover, it has not mandated that baby food manufacturers test finished goods.

**E. Corporate Testing Policies Hide the Truth: In Addition to Hain, Beech-Nut and Gerber Also Fail to Test Finished Product, Risking an Undercount of Toxic Heavy Metals in Their Finished Baby Foods.**

Hain (Earth's Best Organic) revealed to FDA that its policy to test only its ingredients, and not its final product, is underrepresenting the levels of toxic heavy metals in its baby foods. Unfortunately, Hain is not alone. The majority of baby food manufacturers, including Beech-Nut and Gerber, employ the same policy of testing only ingredients.<sup>159</sup> That policy recklessly

<sup>156</sup> *Id.*

<sup>157</sup> Hain, Raw Material Pre-Shipment Test Data History (Dec. 11, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/3_0.pdf)).

<sup>158</sup> *Id.*

<sup>159</sup> Letter from the President and CEO of Beech-Nut Nutrition Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 6, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/6_0.pdf)) ("we do not test finished goods"); Letter from the Chief Executive Officer of Gerber Products Company to Chairman Raja Krishnamoorthi, Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform (Dec. 19,



endangers babies and children and prevents the companies from even knowing the full extent of the danger presented by their products.

As the Hain presentation lays bare, ingredient testing does not work. Hain's finished baby foods had more arsenic than their ingredients 100% of the time—28-93% more inorganic arsenic.<sup>160</sup> That means that only testing ingredients gives the false appearance of lower-than-actual toxic heavy metal levels.

## **VI. RECOMMENDATIONS AND CONSIDERATIONS FOR INDUSTRY, PARENTS, AND REGULATORS: DO HIGHLY TAINTED INGREDIENTS LIKE RICE BELONG IN BABY FOOD?**

Baby food manufacturers hold a special position of public trust. Consumers believe that they would not sell unsafe products. Consumers also believe that the federal government would not knowingly permit the sale of unsafe baby food. As this staff report reveals, baby food manufacturers and federal regulators have broken the faith.

Step one to restoring that trust is for manufacturers to voluntarily and immediately reduce the levels of toxic heavy metals in their baby foods to as close to zero as possible. If that is impossible for foods containing certain ingredients, then those ingredients should not be included in baby foods.

One example of an ingredient that might not be suitable for baby foods is rice. Throughout this report, rice appeared at or near the top of every list of dangerous baby foods.

- For Hain (Earth's Best Organic), organic brown rice was the ingredient that tested highest in inorganic arsenic—309 ppb. Indeed, the majority of Hain ingredients that exceeded 100 ppb inorganic arsenic in testing (13 of 24) were organic brown rice flour.<sup>161</sup>
- For Beech-Nut, the majority of its ingredients that tested over 100 ppb inorganic arsenic (27 of 45) were rice-based (either rice, rice flour, or organic rice).<sup>162</sup>

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2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/7\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/7_Redacted.pdf)) (Gerber's policy is to "regularly test our ingredients, and periodically test... finished goods"); Hain, *Testing And Release Procedure For Baby Food Ingredients* (Dec. 11, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/8\\_Redacted.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/8_Redacted.pdf)) (Hain only tests raw ingredients; their testing policy applies only to ingredients and the vast majority of the testing information they provided to the Subcommittee was raw ingredient testing.).

<sup>160</sup> Hain, *PowerPoint Presentation to Food and Drug Administration: FDA Testing Result Investigation* (Aug. 1, 2019) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2.pdf>).

<sup>161</sup> *Id.*

<sup>162</sup> Beech-Nut, *Raw Material Heavy Metal Testing* (Dec. 6, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/4.xlsx>).

- A significant number of the Nurture products that exceeded 100 ppb inorganic arsenic were rice products.<sup>163</sup>
- Gerber used 67 batches of rice flour with over 90 ppb inorganic arsenic.<sup>164</sup>

Further, rice and rice flour constitute a large proportion by volume of the baby foods that contain them. Therefore, increased toxic heavy metal levels in rice and rice flour could have a significant impact on the safety of the finished product.

If certain ingredients, like rice, are highly tainted, the answer is not to simply lower toxic heavy metal levels as much as possible for those ingredients, the answer is to stop including them in baby foods. The Subcommittee urges manufacturers to make this change voluntarily.

Similar considerations must be made for other ingredients that consistently contain higher levels of toxic heavy metals—ingredients like cinnamon, amylase, BAN 800, and vitamin premix. Manufacturers suggest that these additives, though high in toxic heavy metals, are not a concern because they make up a low percentage of the final food product. However, those manufacturers do not test their final food products, which is the only way to determine safety. Manufacturers should voluntarily commit to testing all of their finished baby food products, as opposed to just the ingredients. If they refuse, FDA should require them to do so.

The Subcommittee recommends the following:

- **Mandatory Testing:** Only one of the companies reviewed by the Subcommittee routinely tests its finished baby foods, even though the industry is aware that toxic heavy metals levels are higher after food processing. Baby food manufacturers should be required by FDA to test their finished products for toxic heavy metals, not just their ingredients.
- **Labeling:** Manufacturers should be required by FDA to report levels of toxic heavy metals on food labels.
- **Voluntary Phase-Out of Toxic Ingredients:** Manufacturers should voluntarily find substitutes for ingredients that are high in toxic heavy metals, or phase out products that have high amounts of ingredients that frequently test high in toxic heavy metals, such as rice.
- **FDA Standards:** FDA should set maximum levels of inorganic arsenic, lead, cadmium, and mercury permitted in baby foods. One level for each metal should apply across all baby foods. The level should be set to protect babies against the neurological effects of toxic heavy metals.
- **Parental Vigilance:** Parents should avoid baby food products that contain ingredients testing high in heavy metals, such as rice products. The implementation of recommendations one through four will give parents the information they need to make informed decisions to protect their babies.

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<sup>163</sup> Nurture, *Heavy Metal Test Results For Baby Food Products* (Dec. 18, 2019) (online at <http://oversight.house.gov/sites/democrats.oversight.house.gov/files/1.xlsx>).

<sup>164</sup> Gerber, *Raw Material Heavy Metal Testing* (Dec. 9, 2019) (online at [https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5\\_0.pdf](https://oversight.house.gov/sites/democrats.oversight.house.gov/files/5_0.pdf)).

## **VII. CONCLUSION**

The Subcommittee's investigation proves that commercial baby foods contain dangerous levels of arsenic, lead, mercury, and cadmium. These toxic heavy metals pose serious health risks to babies and toddlers. Manufacturers knowingly sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever.

Last year, the Trump administration ignored new information contained in a secret industry presentation to federal regulators about toxic heavy metals in baby foods. On August 1, 2019, FDA received a secret slide presentation from Hain, the maker of Earth's Best Organic baby food, which revealed that finished baby food products contain even higher levels of toxic heavy metals than estimates based on individual ingredient test results. One heavy metal in particular, inorganic arsenic, was repeatedly found to be present at 28-93% higher levels than estimated.

The time is now for FDA to determine whether there is any safe exposure level for babies to inorganic arsenic, lead, cadmium, and mercury, to require manufacturers to meet those levels, and to inform consumers through labels.



# EXHIBIT “B”

# What's in my baby's food?

A national investigation finds  
95 percent of baby foods tested  
contain toxic chemicals that lower  
babies' IQ, including arsenic and lead

Report includes safer choices for parents, manufacturers  
and retailers seeking healthy foods for infants

IN PARTNERSHIP WITH



Healthy Babies Bright Futures | Jane Houlihan, Research Director and Charlotte Brody, National Director | October 2019

## ACKNOWLEDGEMENTS

**Authors: Jane Houlihan, MSCE, Research Director, and Charlotte Brody, RN, National Director, Healthy Babies Bright Futures**

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# What's in my Baby's Food?

Our findings show what parents, baby food companies and FDA should do to get toxic heavy metals out of babies' diets

## EXECUTIVE SUMMARY

Parents shop for baby food expecting the nutrition, convenience and baby-tested flavors of store-bought brands. But nearly every jar, pouch and canister also offers something unexpected for a baby's mealtime—traces of heavy metals, including arsenic and lead.

The problem, uncovered nearly a decade ago, is far from solved. New tests of 168 baby foods commissioned by Healthy Babies Bright Futures (HBBF) found toxic heavy metals in 95 percent of containers tested. One in four baby foods contained all four metals assessed by our testing lab—arsenic, lead, cadmium, and mercury. Even in the trace amounts found in food, these contaminants can alter the developing brain and erode a child's IQ. The impacts add up with each meal or snack a baby eats.

Fresh research continues to confirm widespread exposures and troubling risks for babies, including cancer and lifelong deficits in intelligence from exposures to these common food contaminants. Despite the risks, with few exceptions there are no specific limits for toxic heavy metals in baby food.

### PROMISING SIGNS OF PROGRESS MUST ACCELERATE TO PROTECT BABIES.

The government, parents and baby food companies are paying attention. In 2017 the U.S. Food and Drug Administration charged a team of top agency scientists with “reducing exposures... to the greatest extent possible” by prioritizing and modernizing FDA's approaches (FDA 2018a,b). In early 2019 leading baby food companies supported by non-profit organizations, including HBBF, formed a new Baby Food Council that is “seeking to reduce heavy metals in the companies' products to as low as reasonably achievable using best-in-class management practices” (BFC 2019). And since 2011 public health advocates have regularly tested baby foods and educated parents on issues ranging from arsenic and lead in fruit juice (CR 2011,2019a) to arsenic in infant rice cereal (HBBF 2017a, CR 2012) and heavy metals in a range of baby foods (CR 2018, EDF 2017a, Gardener 2018).

Children are better off for the efforts: Current arsenic contamination levels in rice cereal and juice are 37 and 63 percent lower, respectively, than amounts measured a decade ago because of companies' success in reducing metals levels in their food ingredients to comply with draft FDA guidance. They have shifted growing and processing methods, switched plant varieties, and sourced from cleaner fields.

Despite the gains, 19 of every 20 baby foods tested had detectable levels of one or more heavy metals, according to new tests detailed in this study. Only a dramatically accelerated pace at FDA and the fruition of the new Baby Food Council's pursuit of industry-wide change will be enough to finally solve the problem.



### TEST RESULTS: 168 BABY FOODS

**95 percent of baby foods tested contained one or more toxic heavy metals**

*1 in 4 baby foods contained all 4 toxic heavy metals assessed by our testing lab, including arsenic and lead.*

### How many baby foods had multiple heavy metals in a single container?

4 metals	26% of baby foods
3 metals	40%
2 metals	21%
1 metal	8%
0 metals	5% (9 foods)

### In how many baby foods was each heavy metal found?

Arsenic	73% of baby foods
Lead	94%
Cadmium	75%
Mercury	32%

## WHAT'S NEW ABOUT THIS STUDY?

Reports of heavy metals in baby food span nearly a decade. HBBF's study advances this work in 4 ways:

**Many brands tested:** We report on tests of a wider variety of brands than past studies - 61 brands, from big names to niche brands.

**First-ever look at IQ loss for babies:** We include a new study HBBF commissioned from Abt Associates to quantify for the first time the health impacts posed by heavy metals in baby food. This work gives first-ever estimates of the population-wide decline in IQ from children's exposures to lead and arsenic in food, from birth to 24 months of age. It also gives food-by-food rankings to show the 15 foods commonly consumed by babies and young children that drive more than half of the risk (see Findings section of this report).

**Optimized actions for parents:** We streamline advice for parents to cover foods posing the greatest risk to babies, based on the newly released IQ loss findings (Abt 2019b). This allows parents to focus on five actions estimated to provide the greatest benefit for babies' brains.

**New data on industrial pollutants and additive risks:** We also include new data for the industrial chemical perchlorate in baby food. It adds to the risk of IQ loss posed by heavy metals, increasing the urgency for actions to lower the levels of neurotoxic contaminants in baby food.

### PARENTS CAN MAKE FIVE SAFER BABY FOOD CHOICES FOR 80 PERCENT LESS TOXIC METAL RESIDUE.

In the meantime, HBBF's new tests help parents navigate the baby food aisle. We found that simple changes can significantly lower a baby's exposures to heavy metal contamination. Parents shopping for baby food can choose five types of safer items, all readily available, over more contaminated foods (see table below). The safer choices contain 80 percent less arsenic, lead and other toxic heavy metals, on average, than the riskier picks.

Notably, parents can't shop their way out of these exposures by choosing organic foods or by switching from store-bought brands to homemade purees. Heavy metals are naturally occurring in soil and water and are found

at elevated levels in fields polluted by pesticides, contaminated fertilizer, airborne contaminants and industrial operations. Food crops uptake these metals naturally. Leafy greens and root crops like carrots and sweet potatoes retain more than most other types of fruits and vegetables. How the food is processed may also affect the levels. Organic standards do not address these contaminants, and foods beyond the baby food aisle are equally affected.



### Our tests show that simple actions for 5 foods can help lower your babies' exposures to arsenic, lead and other toxic heavy metals

	Higher risk foods for heavy metal exposure	Safer alternative	Toxic heavy metal level
<b>Snacks</b>	Puff snacks (rice)	Rice-free snacks	<b>93% less</b>
<b>Teething Foods</b>	Teething biscuits and rice rusks	Other soothing foods for teething—frozen banana or chilled cucumber	<b>91% less</b>
<b>Cereal</b>	Infant rice cereal	Other infant cereals like multi-grain and oatmeal	<b>84% less</b>
<b>Drinks</b>	Fruit juice	Tap water	<b>68% less</b>
<b>Fruits &amp; Veggies</b>	Carrots and sweet potatoes	Variety: A variety of fruits and veggies that includes carrots, sweet potatoes, and other choices	<b>Up to 73% less</b>

Source: HBBF analysis of tests of 168 baby foods by Brooks Applied Labs, Bothell Washington and FDA market basket data, 2014-2017. Exposures reductions consider average total heavy metal levels in each food (inorganic arsenic, lead, cadmium, mercury) except for cereal, which considers inorganic arsenic only.



### FIFTEEN FOODS ACCOUNT FOR MORE THAN HALF OF THE RISK. RICE-BASED FOODS TOP THE LIST.

Our research substantiates the widespread presence of toxic heavy metals in baby foods found in prior studies, almost no enforceable limits or guidelines on what's allowed, and the common occurrence of arsenic and lead in excess of recommended levels to protect children's health (Table 1, page 12).

Although many foods are contaminated, a few stand out: 15 foods consumed by children under 2 years of age account for 55 percent of the risk to babies' brains, according to a new study commissioned by HBBF and detailed in this report (see Findings section and Appendix E). These include apple and grape juice, oat ring cereal, macaroni and cheese, puff snacks and 10 other foods.

But topping the list are rice-based foods—infant rice cereal, rice dishes and rice-based snacks. These popular baby foods are not only high in inorganic arsenic, the most toxic form of arsenic, but also are nearly always contaminated with all four toxic metals. The new study, completed by the nationally recognized toxicology and economic research firm Abt Associates, estimates that lead and arsenic in rice-based foods account for one-fifth of the more than 11 million IQ points children lose from birth to 24 months of age from all dietary sources. This concentrated risk underscores the need for swift action from FDA and baby food companies to reduce arsenic levels in rice-based foods.

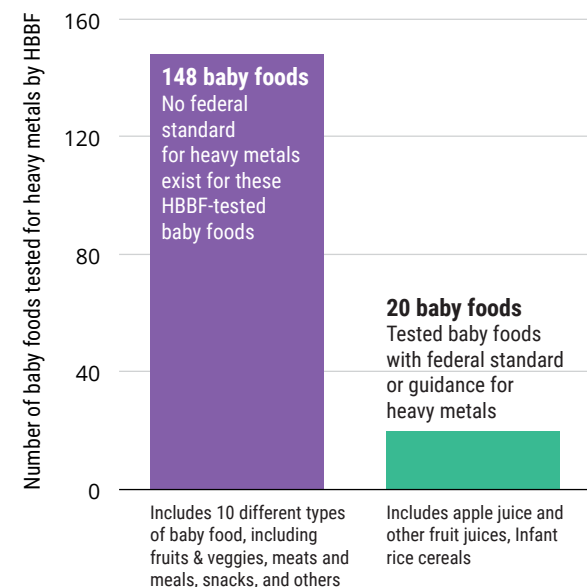
### PARENTS, BABY FOOD COMPANIES, FARMERS, AND FDA ALL HAVE A ROLE IN MEASURABLY REDUCING BABIES' EXPOSURES.

A number of baby food companies are setting their own standards in the absence of enforceable federal limits or guidance. As these initiatives advance, packaged baby foods may be increasingly likely to have lower amounts of heavy metals than homemade varieties.

Our findings raise concerns, but on the spectrum from worry to action, parents can choose to act. While no amount of heavy metals is considered safe, less is better, and parents can lower their babies' exposures by serving a variety of foods and by following the five safer choices for baby foods provided above.

Many factors can influence a child's IQ, from nutrition and genetics to environmental toxins like heavy metals (e.g., Makharia 2016). And many sources ratchet up children's exposures to heavy metals, from drinking water and old plastic toys to lead in dust from chipping paint and soil tracked into the house. But among these factors and sources, heavy metals in food constitute both a significant and a solvable problem. The government, companies and parents can all act — and are, in many cases, already acting — to measurably lower levels in food and to lessen exposures for babies.

### 88 percent of baby foods we tested have no enforceable federal safety limit for arsenic, lead and other heavy metals



## RECOMMENDATIONS

### Baby food companies

Our research shows that baby food companies need to take additional steps to reduce heavy metals in their products. This action is especially important for foods posing the greatest risk to baby's development, with arsenic in rice topping the list, based on a new analysis of children's IQ loss from lead and arsenic in baby food detailed in this study.

To reduce arsenic levels, solutions suggested by FDA and other experts include sourcing rice from fields with lower arsenic levels in soil, growing it with natural soil additives that reduce arsenic uptake by the roots, growing rice strains less prone to arsenic uptake, altering irrigation practices, preparing rice with excess water that is poured off, and blending it with lower arsenic grains in multi-grain products.



We found no evidence to suggest that any brand has reduced heavy metals levels in rice to amounts comparable to those found in other types of grains, despite at least 10 years of significant public attention to the issue that has included widespread consumer alerts and a proposed federal action level (Consumer Reports 2012 and 2014, HBBF 2017, FDA 2016). Four of seven infant rice cereals tested in this study contained inorganic arsenic in excess of FDA's action level.

### FDA

FDA should establish and finalize health-protective standards for heavy metals, prioritizing foods that offer the greatest opportunity to reduce exposure, considering additive effects of the multiple metals detected in foods, and explicitly protecting against neurodevelopmental impacts.

FDA should implement a proactive testing program for heavy metals in foods consumed by babies and toddlers, similar to the Consumer Product Safety Commission's program for children's toys (CPSC 2019).

Because inorganic arsenic in rice is a top source of neurodevelopmental risk for children, FDA should act immediately to establish a health-based limit for this chemical in infant rice cereal and other rice-based foods. In setting its 2016 proposed action level, the agency did not consider IQ loss or other forms of neurological impact, allowed cancer risks far outside of protective limits, and failed to account for children who have unusually high exposures to arsenic in rice (HBBF 2016). Rapid action by FDA to set a protective level will protect children from high levels of arsenic in rice.



### Parents

HBBF encourages parents to follow our simple actions for five foods to lower children's exposures to toxic heavy metals, shown in the Executive Summary and in the report section entitled "What parents can do." The safer choices we list contain 80 percent less arsenic, lead and other toxic heavy metals, on average, than the riskier foods.



## BABY FOOD PURCHASED FOR THE STUDY: STORES, BRANDS, AND FOOD TYPES

We selected 168 individual containers of 13 different food types under 61 baby food brand names. Testing for 4 toxic heavy metals—arsenic, lead, cadmium, and mercury—was performed at Brooks Applied Labs in Bothell, Washington. Only 9 of 168 samples had no detected toxic metals.

**4**  
toxic heavy  
metals tested

**168**  
containers

**61**  
baby food  
brands



and 50 other brands

**13**  
types of baby food



Fruit



Infant formula



Puffs and other snacks



Vegetables



Apple juice



Teething biscuits,  
including rice rusks



Mixed fruits & veggies



100% fruit juice



Infant rice cereal



Meat (jars)



Other drinks for  
toddlers/babies



Infant cereal: multi-  
and non-rice grains



Meals (veggies,  
grains, pasta, meat  
combos)

**14 metropolitan areas  
and 17 retailers from whom  
the foods were purchased:**

- supermarkets
- dollar stores
- baby stores
- superstores



## SUMMARY: EIGHT FINDINGS FROM NEW BABY FOOD TESTS

HBBF and a national, volunteer network of seven other non-profit organizations purchased baby food from stores in 14 metropolitan areas across the country. We purchased foods from 15 retail chains - supermarkets, dollar stores, baby stores, superstores - and two online-only retailers.

We commissioned a nationally recognized laboratory with expertise in heavy metal analysis, Brooks Applied Labs (BAL) near Seattle Washington, to test for four toxic heavy metals—arsenic, lead, cadmium and mercury—in the 168 baby food containers included in this study. We also commissioned this lab to test 25 of those foods, those with the highest arsenic levels, for the specific form of arsenic most toxic to people, inorganic arsenic.

We commissioned a second laboratory, Southwest Research Institute, to test 25 of those foods for an additional neurotoxic contaminant called perchlorate, to further illustrate the need for standards that consider the wide range of neurotoxins in food. Test results, analytical methods and quality control procedures are in Appendices A, C and D. HBBF's analysis of test results shows:

### 1. TOXIC HEAVY METALS WERE FOUND IN NEARLY EVERY BABY FOOD TESTED.

Ninety-five percent of baby foods tested were contaminated with one or more of four toxic heavy metals—arsenic, lead, cadmium and mercury. All but nine of 168 baby foods contained at least one metal; most contained more than one. One in four foods had detectable levels of all four metals, in the same baby food container. We tested a wider range of foods than FDA includes in their annual market basket studies, but our results are consistent with the agencies' findings. In 2017 FDA detected one or more of these four metals in 33 of 39 types of baby food tested (FDA 2019c).

### 2. BABIES ARE EXPOSED DAILY, WITH IMPACTS TO HEALTH.

The four heavy metals we found in baby food have a unique significance: All are developmental neurotoxins (e.g., Grandjean and Landrigan 2006, Sanders 2015). They can harm a baby's developing brain and nervous system, both *in utero* and after birth, for impacts that include the permanent loss of intellectual capacity and behavioral problems like attention-deficit hyperactivity disorder (ADHD). All four metals are linked to IQ loss from exposures early in life. The scientific evidence spans decades and continues to build: at least 23 studies published in the past seven years confirm these four heavy metals' impacts to a child's healthy development (Appendix B). These metals are so prevalent in foods eaten by babies and toddlers that every child could be exposed daily to all three of the most common heavy metals detected in food - lead, arsenic, and cadmium - based on an analysis of federal surveys of children's dietary patterns and heavy metals levels in food (Abt 2019b).

### 3. FEW SAFETY STANDARDS EXIST.

For 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set enforceable limits or issue guidance on maximum safe amounts. In 2016 FDA proposed limiting inorganic arsenic in infant rice cereal to 100 ppb (FDA 2016). Inorganic arsenic exceeded this amount in four of the seven infant rice cereals tested by HBBF (Appendix A). FDA has also proposed limiting inorganic arsenic in apple juice and has issued guidance for limiting lead in fruit juice, but has failed to set specific limits for metals in any other type of baby food (FDA 2013,2014).



**Baby food:**  
Cases of excessive heavy metal contamination, but few safety standards

#### Four of seven rice cereals tested:

Contain inorganic arsenic in excess of FDA's proposed limit of 100 ppb.

#### 88 percent of foods tested:

Lack any federal standards or guidance on maximum safe levels of toxic heavy metals like arsenic and lead.

**4. RECOMMENDED LIMITS ARE OFTEN EXCEEDED.**

Arsenic exceeded FDA's guidance level in four of seven infant rice cereals tested. In the absence of protective federal standards for other baby foods, public health organizations have recommended limits and urged their adoption by companies and FDA. Eighty-three percent of baby foods tested had more lead than the 1-ppb limit endorsed by public health advocates (EDF 2017). Recent FDA tests also found heavy metals in baby food above safe limits, including maximum allowable amounts for children established by the European Food Safety Authority and the U.S. Agency for Toxic Substances and Disease Registry (Spungen 2019). Table 1 (page 12) shows other exceedances.

**5. POPULAR BABY FOODS ESTIMATED TO POSE THE GREATEST RISK ARE AMONG THE MANY FOODS THAT LACK SPECIFIC LIMITS FOR HEAVY METALS.**

HBBF commissioned a new analysis from Abt Associates, a nationally recognized toxicology and economic research group, to accompany our laboratory tests. The work included an assessment of IQ loss attributed to lead and arsenic in baby food and provided food-by-food rankings to show which foods are driving the bulk of the risk. Abt's analysis estimates that children age 0 to 24 months lose more than 11 million IQ points from exposure to arsenic and lead in food. Just 15 foods consumed by these children account for 55 percent of the total estimated IQ loss. Heavy metals in 10 of these foods are unregulated, lacking any FDA guidance or regulation to limit the levels. Abt's analysis is described in Appendix E. The analysis considers all foods consumed by children under 2, from store-bought and homemade foods for babies to the wider range of packaged and homemade foods that toddlers eat.

Milk and infant formula appear on the list of 15 foods not because of high metals levels—arsenic and lead concentrations are relatively low in both compared to some other types of baby food, according to HBBF and FDA tests—but because American children drink so much of them. These are nutritious foods, and there is no action needed

**Results of IQ analysis: 15 foods account for 55% of total IQ loss from children's dietary exposures to arsenic and lead in baby food**

<b>Food consumed by child age 0 - 24 months</b>	<b>Percent of total harm (fraction of total IQ points lost for children under 2, from lead and arsenic in food)</b>	<b>Primary toxic metal of concern</b>
Rice dishes, including with beans & veggies	10.0%	<b>Arsenic</b>
Milk, whole*	8.4%	<b>Arsenic</b>
Rice, white and brown	7.0%	<b>Arsenic</b>
Apple juice	6.1%	<b>Arsenic</b>
Infant formula*	5.3%	<b>Lead</b>
Fruit juice blend (100% juice)	4.1%	<b>Arsenic</b>
Infant rice cereal	2.7%	<b>Arsenic</b>
Grape juice	2.0%	<b>Lead and arsenic</b>
Cheerios and other oat ring cereals	1.6%	<b>Arsenic</b>
Sweet potato (baby food)	1.6%	<b>Lead and arsenic</b>
Soft cereal bars and oatmeal cookies	1.4%	<b>Arsenic</b>
Macaroni and cheese	1.4%	<b>Lead and arsenic</b>
Puffs and teething biscuits	1.3%	<b>Lead and arsenic</b>
Bottled drinking water	1.2%	<b>Arsenic</b>
Fruit yogurt	1.2%	<b>Lead</b>

\*Note: Milk and infant formula appear on the list not because of high metals levels — arsenic and lead concentrations are relatively low in both compared to some other types of baby food, according to HBBF and FDA tests — but because American children drink so much of them. These are nutritious foods, and there is no action needed by parents to change what they serve their children.

Source: HBBF-commissioned analysis of federal data in national surveys of food contamination and consumption (see Appendix E and Abt 2019b for details).

by parents to change what they serve their children. But FDA action to set limits in milk and formula for arsenic and lead—and cadmium as well, which is often detected—would create benefits extending to millions of children.

Similarly, bottled water appears on the list not because high metals levels are common, but because so many children drink it. Bottled water is no safer than filtered tap water and generates plastic waste that is easily avoided by choosing tap water.

Two results stand out from the IQ analysis. First, during the first two years of life, American children lose four times more IQ points from arsenic contamination in food than from lead contamination. Second, rice-based foods—including infant rice cereal, rice dishes and rice-based snacks—contribute nearly one-fifth of the total estimated IQ loss. These results show a crucial need for swift action from FDA and baby food companies to dramatically reduce arsenic levels in rice-based foods.

## 6. ADDITIONAL BABY FOOD TESTS BY HBBF DETECTED ANOTHER NEUROTOXIC CONTAMINANT—PERCHLORATE.

HBBF's tests uncovered one additional neurotoxin in food. We sent new containers of 25 of the foods tested for heavy metals to a separate laboratory, to be analyzed for a neurotoxic pollutant called perchlorate. The lab detected it in 19 of 25 foods tested (Appendix D and SWRI 2019). All 19 foods with detectable perchlorate also contained heavy metals, and 12 contained all four heavy metals included in our tests.

Perchlorate disrupts thyroid functions crucial to brain development and has been linked to IQ loss among children born to mothers with thyroid dysfunction, who are more vulnerable to perchlorate toxicity (Taylor 2014). It is a rocket fuel component used since the Cold War. In 2005 FDA approved its use as an antistatic in plastic food packaging, and in 2016 expanded the approval to cover dry food handling equipment. Perchlorate is also a degradation product of hypochlorite used to disinfect food processing equipment. Levels in children's food increased dramatically from 2005 to 2012 (Abt 2016, EDF 2017b).

Our tests did not find the high spikes seen previously (EDF 2017b), but our results suggest a prevalence that could pose risks during pregnancy and infancy. The results support the need for FDA to ban all food uses, especially given that perchlorate adds to neurodevelopmental risks already imposed by the heavy metal contamination in baby food.

## 7. EXPOSURES AND IMPACTS ADD UP, INCREASING URGENCY FOR ACTION.

Heavy metals and perchlorate are not the only food contaminants raising the specter of IQ loss and other neurodevelopmental deficits for babies. Among recent examples, apples and spinach are often tainted with organophosphate pesticides, cheeses including mac 'n' cheese powder contain phthalate plasticizers, and

## New tests by HBBF find perchlorate contamination in 19 of 25 baby foods

### Number of baby foods with perchlorate, of total tested (and maximum level found):

Infant rice cereal:	2 of 5 - 7.1 ppb
Other infant cereals:	9 of 9 - 7.8 ppb
Infant formula:	2 of 3 - 11.4 ppb
Fruits & vegetables:	4 of 4 - 19.8 ppb
Snacks:	2 of 4 - 4.6 ppb

See Appendix D for details. "ppb" = parts per billion, or micrograms per kilogram.

a wide range of breakfast cereals, grains and beans are contaminated with the pesticide glyphosate (Roundup). All of these pollutants and pesticides are neurotoxic or linked to babies being born small (from mothers' exposures), with resulting risks for lower IQ and other neurological or behavioral impacts (e.g., Flensburg-Madsen 2017, Parvez 2018, Gillam 2017, FOE 2019, EWG 2019 and 2020, CSFPP 2017).

## 8. ACTIONS NEEDED BY FDA AND BABY FOOD COMPANIES GO BEYOND HEAVY METALS.

Exposures and impacts add up. The new analysis of children's IQ loss (Abt 2019b) provides a starting point for understanding these combined impacts. It considers one health impact—IQ loss—associated with 2 metals in food, arsenic and lead. Mercury in baby food would also contribute to IQ loss, and preliminary data suggests that cadmium would as well; for these metals, data were not

yet available to assess the IQ drop expected with each successive exposure for a child. Those data are urgently needed. And other neurotoxic pollutants in food would add to the cumulative impacts, each time a child eats.

For parents, the answer is not switching to homemade purees instead of store-bought baby foods. Federal data shows that baby food sometimes has higher levels and sometimes lower levels of heavy metals, compared to comparable fresh or processed foods purchased outside the baby food aisle. For example, peaches and green beans from the baby food aisle are less likely to contain detectable levels of lead than canned versions of these foods, while carrot and sweet potato baby foods have higher lead detection rates than their peeled, fresh counterparts (EDF 2019b).

In most cases it's not the amount of a particular contaminant in baby food that causes concern. Our tests show that most metals are at low levels and by themselves in any given food raise little concern. It's babies' daily exposures to the many neurotoxins in baby foods that drive the urgency for action. When FDA and baby food companies address one contaminant in one type of food, children benefit. But truly protecting children necessitates addressing the many contaminants that collectively harm a child's healthy development. HBBF supports the FDA's and baby food companies' efforts to continually lower the levels of heavy metals and other neurotoxic contaminants in all baby foods. Specific recommendations include:

### FDA:

HBBF agrees with the mission of FDA's Toxic Elements Working Group to reduce exposures to the greatest extent possible. We urge the agency to:

- Set health-protective standards for heavy metals, prioritizing foods that offer FDA the greatest opportunity to reduce exposure, considering additive effects of the multiple metals detected in foods, and explicitly protecting against neurodevelopmental impacts.

- Strengthen and finalize standards for arsenic in apple juice and infant rice cereal, and expand the range of foods covered. HBBF supports recommendations for a 3-ppb inorganic arsenic standard and 1-ppb lead standard that apply to all fruit juice, and a health-protective standard for arsenic in infant rice cereal and all other rice-based foods.
- Implement a proactive testing program for heavy metals in foods consumed by babies and toddlers, similar to the Consumer Product Safety Commission's program for children's toys (CPSC 2019).
- Ensure lead is not present in food contact materials where it could get into food.
- Establish a goal of no measurable amounts of cadmium, lead, mercury, and inorganic arsenic in baby and children's food, in recognition of the absence of a known safe level of exposure, and work with manufacturers to achieve steady progress.

#### **Baby food companies:**

HBBF is a member of the Baby Food Council and supports its goal to reduce heavy metals in baby food to levels as low as reasonably achievable. Other companies can join this effort, as described below from the organization's charter:

*The Baby Food Council is a group of infant and toddler food companies, supported by key stakeholders, seeking to reduce heavy metals in the companies' products to as low as reasonably achievable usage best-in-class management practices. The Council was created in January 2019 in partnership with Cornell University and*

*the Environmental Defense Fund. All companies that source ingredients, manage the upstream supply chain, and nationally market foods for children six to 24 months of age in the United States are welcome to participate in the Council. Since its creation, Healthy Babies Bright Futures has joined the Council as a member and the American Academy of Pediatrics and the Food and Drug Administration have agreed to serve as technical advisors to the effort. For more information, contact Randy Worobo of Cornell University at [rww8@cornell.edu](mailto:rww8@cornell.edu).*

*– The Baby Food Council, 2019*

HBBF urges all baby food companies to establish a goal of no measurable amounts of cadmium, lead, mercury, and inorganic arsenic in baby and children's food, in recognition of the absence of a known safe level of exposure, and to achieve steady progress toward that goal.



## WHAT PARENTS CAN DO

**THE SAFER FOOD CHOICES OUTLINED HERE HAVE 80 PERCENT LOWER HEAVY METAL LEVELS, ON AVERAGE, THAN THE HIGHER RISK FOODS.**

An abundance of online advice instructs parents on ways to reduce children's exposures to heavy metals in foods. HBBF has streamlined those tips down to simple actions that cover five foods posing high risks to babies' neurological development, based on Abt's new analysis (Abt 2019b). This allows parents to focus on changes that are estimated to provide the greatest benefit for babies' brains.

*Note: For each pair of foods shown, concentrations shown and the comparative term "less toxic metals" are based on the average of the sum of four metals (inorganic arsenic, lead, cadmium and mercury) for the available samples of each food, unless noted otherwise. Averages were computed using data from the current study combined with data from FDA's market basket study (the Total Diet Study, FDA 2014-2017). The abbreviation "ppb" refers to parts per billion.*

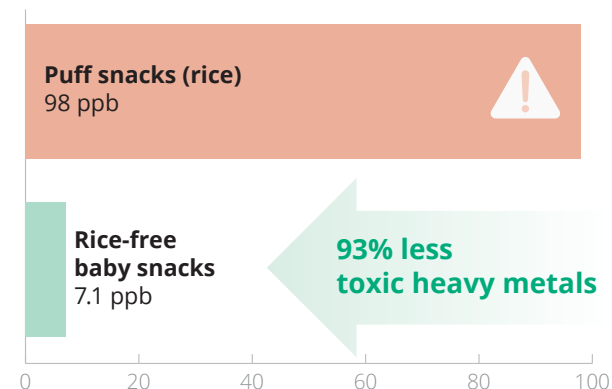
**1 Puffs and other snacks made with rice flour** contain arsenic, lead and cadmium at relatively high levels compared to other baby foods. Parents can reduce children's exposures by choosing rice-free packaged snacks instead, which have 93 percent less toxic metal residues, on average. Multi-grain snacks that include rice would also have lower levels than snacks containing rice as the only grain. Other alternatives come from Consumer Reports, which recommends snacks that are rich in nutrients and low in metals, and that can be prepared and served to be appropriate for young children (such as soft-cooked, diced or mashed): **apples, applesauce (unsweetened), bananas, barley with diced vegetables, beans, cheese, grapes (cut lengthwise), hard-boiled eggs, peaches, and yogurt** (CR 2018). A caveat for non-rice snacks—HBBF tests showed lower metals levels in non-rice snacks, including crackers, bars and yogurt snacks, but federal data shows relatively high arsenic in a popular snack we did not test: oat ring cereals like Cheerios (FDA 2019c). We recommend avoiding this choice for snacks.

**2 Teething biscuits and rice rusks** often contain arsenic, lead, and cadmium. They also lack nutrients and can cause tooth decay. Doctors and dentists recommend other solutions for baby teething pain (Colgate 2020, AAP 2020). Options include **a frozen banana, a peeled and chilled cucumber, a clean, cold wet washcloth or spoon**. Healthcare professionals advise parents to stay with their baby to watch for any choking.

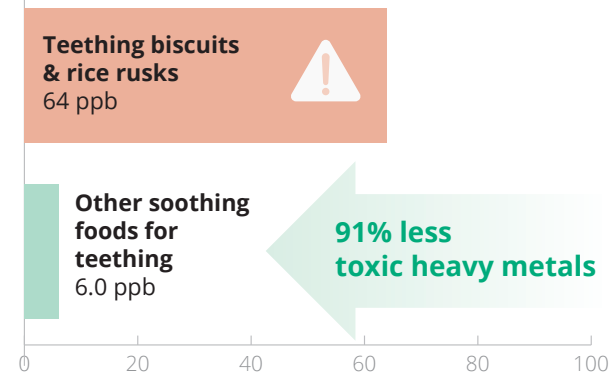
**3 Infant rice cereal** is the top source of arsenic in infant's diets. HBBF's 2017 study of infant cereals found that **non-rice and multi-grain varieties** on grocery shelves nationwide—including **oatmeal, corn, barley, quinoa, and others**—contain 84 percent less inorganic arsenic than leading brands of infant rice cereal, on average. Federal data shows 64 percent less total heavy metals, on average, in infant non-rice cereals compared to rice varieties. The alternates include reliable and affordable choices for parents seeking to reduce infants' exposures to arsenic (HBBF 2017a).

**Rice** is a leading source of arsenic exposure for young children. Parents can serve other grains like oats, wheat and barley instead of rice to help cut their family's exposures. Cooking rice in extra water that is poured off before serving can cut the arsenic levels by up to 60 percent, according to FDA studies (FDA 2016). The lowest arsenic levels are found in basmati rice grown in California, India, and Pakistan. White rice has less arsenic than brown rice. Rice from Arkansas, Louisiana, Texas, or simply "U.S." has the highest levels, according to testing by Consumer Reports (CR 2014).

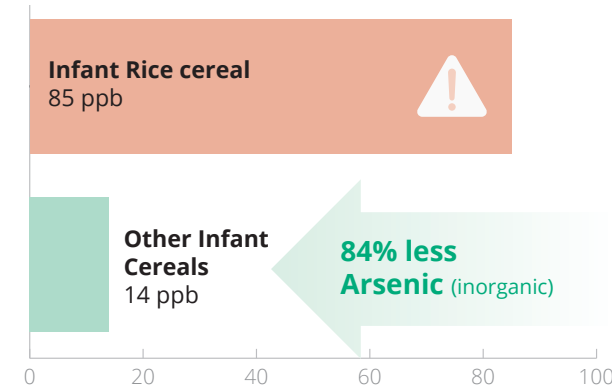
### 1 SNACKS

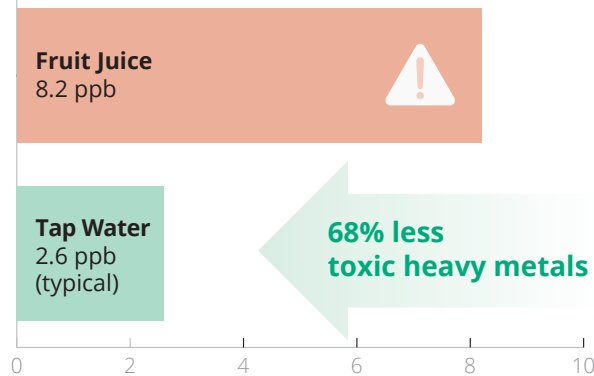


### 2 TEETHING FOODS

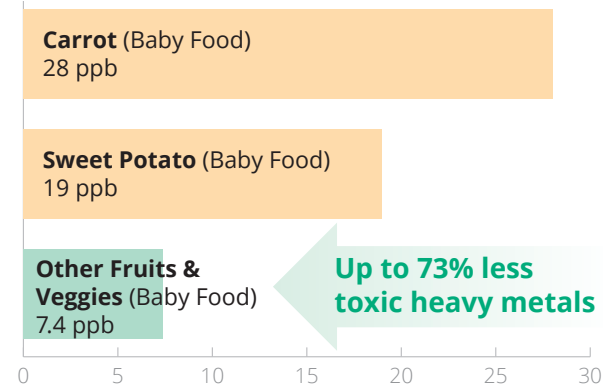


### 3 CEREAL



**4 DRINKS**

**4 Apple, pear, grape and other fruit juices** contain traces of lead and arsenic. Levels aren't as high as in some other foods, but toddlers drink juice often, so it's a top exposure source. **Tap water** is a better drink for thirsty toddlers. Another alternative is **whole or pureed fruits** (like applesauce), which offer more fiber and nutrients than juice. The American Academy of Pediatrics warns parents of juice's high caloric and sugar content. It advises no fruit juice for children under 1 year of age, and half a cup or less daily for children under 3. AAP recommends that if fruit juice is given, it should be offered as part of a meal, not diluted with water and sipped over time, because of tooth decay risks (AAP 2017b, Heyman 2017).

**5 FRUITS & VEGGIES**

**5 Carrots and sweet potatoes** are a great source of Vitamin A and other nutrients your baby needs. But they also contain higher levels of lead and cadmium than other fruits and vegetables, on average. Yet they are an important part of a child's diet, and a common baby food ingredient. **Variety is the solution:** parents can serve these vegetables along with other fruits and vegetables during the week, for benefits without the excess risk.

**Table 1: Three take-aways:**  
Our research substantiated the widespread presence of four toxic heavy metals in baby foods, almost no enforceable federal standards to limit what’s allowed, and the common occurrence of arsenic and lead in excess of recommended levels to protect children’s health.

What did our tests of 168 baby foods find?	1. Widespread detections of toxic heavy metals 95 percent of baby foods tested were contaminated with one or more toxic heavy metals, including arsenic and lead. No food type was free of contamination.				2. Few enforceable limits for baby food For 10 of 13 baby food types tested, there is no FDA guidance on safe limits for toxic heavy metals.				3. Gaps in protecting babies’ health 83% of baby foods tested had more lead than the 1-ppb limit endorsed by public health advocates. Arsenic exceeded FDA’s guidance level in 4 of 7 infant rice cereals tested.			
	Our tests found four toxic heavy metals in baby food (▲ = detected)				Has FDA issued a safe limit for toxic heavy metals in the baby foods we tested? Limits endorsed by health organizations are also shown.				Did our test results exceed recommended safe limits for baby food? (▲ = safe level exceeded in HBBF tests)			
	Arsenic	Lead	Cadmium	Mercury	Arsenic (inorganic)	Lead	Cadmium	Mercury	Arsenic	Lead	Cadmium	Mercury
Puffs and other snacks	▲ 19 of 21 foods	▲ 21 of 21 foods	▲ 19 of 21 foods	▲ 14 of 21 foods	No	No 1 ppb (EDF)	No	No	No limit exists	▲ All 21 foods exceed 1 ppb limit.	No limit exists	No limit has been set for mercury in baby food, but levels are low compared to amounts in canned tuna and other seafood.
Teething biscuits, including rice rusks	▲ 10 of 10 foods	▲ 10 of 10 foods	▲ 10 of 10 foods	▲ 10 of 10 foods	No	No 1 ppb (EDF)	No	No	No limit exists	▲ All 10 foods exceed 1 ppb limit.	No limit exists	
Infant formula	▲ 8 of 13 containers	▲ 13 of 13 containers	▲ 8 of 13 containers	▲ 1 of 13 containers	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 12 of 13 containers exceed 1 ppb limit.	No limit exists	
Infant rice cereal	▲ 7 of 7 cereals	▲ 7 of 7 cereals	▲ 7 of 7 cereals	▲ 7 of 7 cereals	Yes - limits: 100 ppb (FDA) 25 ppb (HBBF)	No 1 ppb (EDF)	No	No	▲ 7 cereals tested. 4 exceed FDA limit. 7 exceed HBBF limit.	▲ All 7 cereals exceed 1 ppb limit.	No limit exists	
Infant cereal - multi & single non-rice grains	▲ 11 of 11 cereals	▲ 10 of 11 cereals	▲ 11 of 11 cereals	▲ 2 of 11 cereals	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 9 of 11 cereals exceed 1 ppb limit.	No limit exists	
Meals (veggies, grains, pasta, meat combos)	▲ 7 of 10 foods	▲ 10 of 10 foods	▲ 10 of 10 foods	▲ 2 of 10 foods	No	No 1 ppb (EDF)	No	No	No limit exists	▲ All 10 meals exceed 1 ppb limit.	No limit exists	
Veggies	▲ 25 of 38 containers	▲ 38 of 38 containers	▲ 34 of 38 containers	▲ 9 of 38 containers	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 33 of 38 containers exceed 1 ppb limit.	No limit exists	
Fruits	▲ 8 of 16 containers	▲ 10 of 16 containers	▲ 5 of 16 containers	▲ 3 of 16 containers	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 8 of 16 containers exceed 1 ppb limit.	No limit exists	
Mixed fruits and veggies	▲ 10 of 14 containers	▲ 14 of 14 containers	▲ 12 of 14 containers	▲ 3 of 14 containers	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 11 of 14 containers exceed 1 ppb limit.	No limit exists	
Meat (jars)	▲ 1 of 6 jars	▲ 5 of 6 jars	▲ 1 of 6 jars	▲ 1 of 6 jars	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 2 of 6 jars exceed 1 ppb limit.	No limit exists	
Apple juice	▲ 3 of 4 juices	▲ 4 of 4 juices	None found 0 of 4 juices	None found 0 of 4 juices	Yes - limits: 10 ppb (FDA) 3 ppb (CR)	Yes - limits: 50 ppb (FDA) 1 ppb (AAP)	No 1 ppb (CR)	No	▲ 4 juices tested. 0 exceed FDA’s 10 ppb limit. 2 exceed a 3 ppb limit.	▲ 4 juices tested. 0 exceed FDA’s 50 ppb limit. 1 exceeds 1 ppb limit.	★ 4 juices tested. 0 exceed 1 ppb limit.	
Juice - 100% fruit, non-apple	▲ 4 of 5 juices	▲ 4 of 5 juices	▲ 2 of 5 juices	None found 0 of 5 juices	No 3 ppb (CR)	Yes - limits: 50 ppb (FDA) 1 ppb (AAP)	No 1 ppb (CR)	No	▲ 5 juices tested. 2 exceed 3 ppb limit.	▲ 5 juices tested. 0 exceed FDA’s 50 ppb limit. 3 exceed AAP limit.	★ 5 juices tested. 0 exceed 1 ppb limit.	
Other drinks for babies and toddlers	▲ 3 of 5 drinks	▲ 4 of 5 drinks	▲ 2 of 5 drinks	None found 0 of 5 drinks	No	No 1 ppb (EDF)	No	No	No limit exists	▲ 2 of 5 drinks exceed 1 ppb limit.	No limit exists	

Information on safety standards and recommended limits can be found in these references: FDA – 100 ppb arsenic in infant rice cereal (FDA 2016); HBBF (Healthy Babies Bright Futures) – 25 ppb arsenic in infant rice cereal (HBBF 2017a,b); FDA – 10 ppb arsenic in apple juice (FDA 2013); CR (Consumer Reports) – 3 ppb arsenic in apple and other fruit juice (CR 2019a,b); FDA – 50 ppb limit for lead in fruit juice (FDA 2004); CR and EDF (Environmental Defense Fund) – endorsement of AAP (American Academy of Pediatrics) 1-ppb lead-in-water limit to apply to fruit juice (CR 2019a,b; AAP 2017a); EDF – goal of 1 ppb for lead in baby food (EDF 2017a).



## HEALTH RISKS: THE SCIENTIFIC EVIDENCE

Fresh research continues to confirm widespread exposures and troubling risks for babies exposed to the four heavy metals included in this study, including at least 23 peer-reviewed studies published in the past seven years revealing IQ loss, attention deficits, and other learning and behavioral impacts among children who are exposed through food and other sources (Appendix B). Three of the metals, arsenic, lead and cadmium, are also potent human carcinogens.

Widespread exposure to toxic heavy metals shifts the population-wide IQ curve down. It nudges more children into special education, and ratchets down the IQ of the most creative and intellectually gifted children. For an individual child, the harm appears to be permanent (e.g., Grandjean and Landrigan 2014, Wasserman 2007 and 2016, Hamadani 2011).

Instead of overt poisoning, the low, daily exposures children face from heavy metals in food and other sources create “subclinical decrements in brain function” with impacts on a global scale. Scientists write that the exposures “diminish quality of life, reduce academic achievement, and disturb behaviour, with profound consequences for the welfare and productivity of entire societies” (Grandjean and Landrigan 2014).



### ARSENIC

Arsenic widely contaminates food and drinking water from its long-time use as a pesticide and an additive in animal feed, from its release at mining and industrial operations, and from natural sources. Arsenic causes bladder, lung and skin cancer and also harms the developing brain and nervous system. In the peer-reviewed scientific literature, at least 13 studies link arsenic to IQ loss for children exposed in utero or during the first few years of life (Rodriguez-Barranco 2013).

Among evidence supporting arsenic’s ability to harm the brain is a 2014 assessment of nearly 300 third to fifth graders in Maine, finding an average loss of 5-6 IQ points among those who drank well water contaminated with arsenic at or above 5 parts per billion. This level is common in some parts of the U.S. and is lower than the legal limit in public water supplies (10 parts per billion) (Wasserman 2014). Studies find lasting impacts when children are exposed to arsenic early in life, including persistent IQ deficits in children two years after their polluted drinking water was replaced, cognitive deficits among school-age children exposed early in life, and neurological problems in adults who were exposed to arsenic-poisoned milk as infants (Wasserman 2007 and 2016, Hamadani 2011, Tanaka 2010). There is no evidence that the harm caused by arsenic is reversible.

### LEAD

Over the past 40 years lead has been restricted in children’s toys and phased out of gasoline, pesticides, paint, and food contact surfaces, including lead solder from cans. But lead that lingers in homes, soil, and water remains a festering problem. The toxic metal continues to contaminate the blood of nearly every child tested. Although exposures are lower now than in the past, lead-induced brain damage still accounts for an estimated 23 million IQ points lost among children under five (Bellinger 2012). Even very low exposure

levels cause lower academic achievement, attention deficits and behavior problems. No safe level of exposure has been identified.

Evidence of lead’s toxicity spans decades. Among recent studies are two that included 80,000 Detroit and Chicago school children, 3rd grade through middle school, whose standardized math and reading tests were correlated to their blood lead levels measured at birth or early childhood. “Early childhood lead exposure is associated with poorer achievement... even at very low blood lead levels,” concluded one of the research teams (Zhang 2013, Evens 2015).

Lead widely contaminates food from its long-time use as a pesticide, its presence in food processing equipment (in older brass, bronze, plastic, and coated materials), and its presence at elevated levels in soil, either natural or accumulated from industrial pollution. In October 2018 FDA cut in half its maximum daily intake limit for lead in children’s food. An estimated 2.2 million children six years or younger exceed the new intake limit (EDF 2019a).

### Beyond Food: Other sources of lead exposure

For many children the biggest source of lead exposure is not food, but lead paint in homes built before 1978. Lead from chipping and peeling paint builds up in house dust and sticks to children’s hands. It also flakes off of a home’s exterior to contaminate soil in the yard.

To learn if you have lead paint, have your home inspected by a licensed lead inspector. You can also use a simple test kit sold at many hardware stores. Learn more: <https://www.epa.gov/lead/protect-your-family-exposures-lead>

**CADMIUM**

Cadmium is a heavy metal linked to neurotoxicity and cancer, and to kidney, bone and heart damage. It has many industrial uses and is a common contaminant in food and the environment. It lacks the name recognition of arsenic and lead, but may deserve an equal share of attention from parents, companies, and regulators, since it also displays a troubling ability to cause harm at low levels of exposure.

A 2015 review of recent scientific literature identified 16 studies on the neurotoxic impacts of cadmium on children. Among these is research by Harvard scientists reporting a tripling of risk for learning disabilities and special education among children with higher cadmium exposures, at levels common among U.S. children and previously thought to be safe (Ciesielski 2012).

A 2019 study by FDA found that cadmium in food exceeds amounts safe for children: In its 2014-2016 market basket tests, FDA detected cadmium in 65 percent of nearly 3000 food samples tested, and estimated that children's average exposures exceed safe limits established by both the European Food Safety Authority and the U.S. Agency for Toxic Substances and Disease Registry (Spungen 2019).

**MERCURY**

Mercury is a global pollutant released from coal-fired power plants, mining operations and other sources. It contaminates the biosphere and the food chain. Seafood is the dominant source of mercury exposure for children and adults. It contains a particularly toxic form of mercury called methylmercury that increases risk for cardiovascular disease for adults and poor performance on tests of vision, intelligence, and memory for children exposed in utero.

Evidence that the developing brain is particularly sensitive to mercury extends back decades, covering two mass poisonings and major longitudinal studies of lower exposures from seafood, among other research (NAS 2000). Recently, scientists found a four-fold higher risk for IQ scores under 80, the clinical cut-off for borderline intellectual disability, among school-age children exposed to high levels of mercury in utero (Jacobsen 2015).

Although mercury was detected in 32 percent of the 168 baby foods tested in this study, levels were far lower than typical amounts in tuna and other seafood. FDA and EPA's joint advisory gives safer seafood choices for pregnant women and young children (EPA and FDA 2019). A number of NGOs have published more conservative advice to protect women who eat seafood frequently (EWG 2014, MBASW 2020). Mercury levels in canned tuna exceed the legal limit under California's Proposition 65, but an attempt to require the law's mandated warnings on canned tuna failed in 2006 when an appeals court found that the California law was preempted by the FDA/EPA seafood advisory (Kone 2006).

## SAFETY STANDARDS

The four toxic metals covered in this study—arsenic, lead, cadmium and mercury—were regulated decades ago in sources as wide-ranging as drinking water, gasoline and children’s toys.

Regulations have also eliminated lead from food contact surfaces, including lead solder from food cans (Bolger 1996). But they remain without an enforceable limit or guideline in nearly every type of baby food, despite being widely acknowledged as toxic during a child’s development and prevalent in popular baby and toddler foods.

All four metals are neurotoxic. Three—arsenic, lead and mercury—have been shown to permanently reduce children’s IQ. Three are also human carcinogens, arsenic, cadmium and lead.

FDA can use its testing programs, recall authority, and guidance to industry, among other tools, to characterize and control heavy metal levels in food. The agency tests a fraction of imported food in their Import Program, prioritizing food likely to pose risks to consumers, including those with high heavy metals levels. Federal law gives FDA the authority to require a recall of food it deems to be adulterated, that “bears or contains any poisonous or deleterious substance which may render it injurious to health,” including heavy metals. In the past three years FDA has issued recalls for eight foods with excessive lead or arsenic, none of which were baby foods (FDA 2019d). In September 2019 the agency issued an import alert for lead and arsenic in grape and pear juice concentrates, advising their inspectors to target these products for testing (FDA 2019e).

FDA also tests a variety of foods on store shelves in their Total Diet Study market basket program, focusing on foods that are commonly eaten or likely to have high levels of metals (FDA 2019c). FDA’s compliance program conducts occasional testing programs that target select, high-risk foods. These data have helped FDA prioritize its work to reduce heavy metals levels in baby food.

In 2016 FDA proposed limiting inorganic arsenic in infant rice cereal to 100 ppb (FDA 2016). Inorganic arsenic exceeded this amount in four of the seven infant rice cereals tested by HBBF.

FDA has also proposed limiting inorganic arsenic in apple juice and has issued guidance for limiting lead in fruit juice (FDA 2004, 2013), but has failed to set limits for metals in any other type of baby food.

Despite FDA’s many areas of authority and its recent emphasis on reducing exposures to heavy metals, for 88 percent of baby foods tested by HBBF—148 of 168 baby foods—FDA has failed to set enforceable limits or issue guidance on maximum safe amounts.

And none of the agency’s existing guidance considers the additive neurological impacts of multiple metals in baby food.

### **FDA’S PROPOSED GUIDANCE FOR ARSENIC IN INFANT RICE CEREAL REMAINS UNFINALIZED DESPITE PROMISES TO COMPLETE IN 2018.**

FDA’s 2016 proposed limit for inorganic arsenic in infant rice cereal—its 100 parts-per-billion “action level”—falls short of what is needed to protect children. In proposing the level, FDA did not consider IQ loss or other forms of neurological impact, allowed cancer risks far outside of protective limits, and failed to account for children who have unusually high exposures to arsenic in rice (HBBF 2016, HBBF 2017a).

And if the agency finalizes the action level, it will serve only as guidance to the infant cereal industry, not as a standard that FDA is required to enforce. Instead, FDA can choose whether or not to enforce an action level, at its own discretion.

HBBF has advocated that FDA finalize a more protective standard that protects against neurological harm during development and that applies to all rice-based foods eaten by babies and pregnant women. HBBF has also called on cereal companies to reduce levels to 25 ppb, an amount typical of levels in multi-grain cereals (HBBF 2017a,b).

Altogether, six of 30 rice-based baby foods tested by HBBF contained inorganic arsenic above the 100-ppb limit proposed for infant rice cereal—four infant rice cereals and two puff snacks (Appendix A).

### **FDA'S PROPOSED GUIDANCE FOR ARSENIC IN APPLE JUICE REMAINS UNFINALIZED DESPITE PROMISES TO COMPLETE IN 2018.**

In 2013 FDA proposed limiting inorganic arsenic in apple juice to 10 ppb, the federal government's standard for arsenic in drinking water (FDA 2013). This limit still has not been finalized. Consumer Reports, a long-time advocate for reducing toxic metals in food, has argued for a more protective limit of 3 ppb, and for inclusion of other high-arsenic juices, like grape and pear juice (CR 2019a,b).

Arsenic in juice exceeded CR's recommended limit of 3 ppb in two of nine juices tested by HBBF, a white grape juice and an apple juice.

FDA has also issued guidance to limit lead in fruit juice (FDA 2004). This level, 50 ppb, is 3.3 times higher than the federal drinking-water action level, 10 times more than the FDA's bottled-water standard, and 50 times higher than the American Academy of Pediatrics' recommended lead-in-water limit for school drinking fountains.

Experts at Consumer Reports and the Environmental Defense Fund back a far lower limit, arguing for a 1-ppb cap to match the American Academy of Pediatrics' recommended maximum for lead in school drinking fountains (CR 2019a,b; AAP 2017).

While none of the fruit juices tested by HBBF topped FDA's 50-ppb limit, four of nine juices contained more lead than the recommended 1 ppb cap, with a maximum of over 11 ppb in a white grape juice marketed for toddlers. At these levels, the many children who regularly drink juice are getting too much lead. Eighty percent of American families with toddlers and babies serve juice to children. Three-quarters of those families serve it daily; their children face the highest risks (CR 2019b).

### **PROMISING PROGRESS AT FDA**

In April 2017 FDA's Center for Food Safety and Applied Nutrition (CFSAN) announced it had established a Toxic Elements Working Group to modernize safety standards for the toxic metal mixtures Americans are exposed to, including in food. The working group is charged with charged with "achiev[ing] the public health goal of reducing exposure... to the greatest extent possible" (FDA 2017, 2018a,b).

Although FDA has not yet introduced new standards as a result of the initiative, it has made progress. It has lowered the maximum allowed daily lead intake for children from 6 to 3 micrograms per day (ug/day) and set a cap of 12.5 ug/day for women who are pregnant or nursing. These new "Interim Reference Levels" are a critical first step for lowering allowable lead levels in food (FDA 2019b). FDA has also launched new research to understand children's exposures to combinations of metals, and the impacts of these mixtures on the developing brain and nervous system (e.g., Spungen 2019). The agency missed its commitment to finalize the arsenic guidelines for infant rice cereal and apple juice by the end of 2018.

Heavy metal mixtures like those found in baby food pose risks to the developing brain. Setting protective, health-based limits for these contaminants presents an opportunity to make a significant difference in children's health.

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## APPENDIX A: LABORATORY TEST RESULTS FOR HEAVY METALS

Results for analysis of heavy metals in a variety of baby foods are listed below. Foods were tested for total recoverable arsenic; speciated arsenic (total inorganic arsenic is shown below); and total recoverable lead, cadmium, and mercury. Testing was commissioned by HBBF and performed by Brooks Applied Labs in Bothell, Washington in 2019. Appendix C provides a summary of analytical methods.

The qualifier “<” indicates that the concentration was below the method detection limit, while The symbol “\*” indicates test results that are estimated, that fall between the limit of detection and the limit of quantification. The qualifier “--” indicates that the analysis was not performed.

About estimated values: The table below shows results for all target analytes detected by the lab’s instruments. Estimated values shown with the qualifier “\*” have greater uncertainty than other results. The starred (\*) values are the lab’s best estimates of concentration, but the actual amounts may be higher or lower than these best estimates. These estimated test results are near the test’s detection limit. They are higher than the detection limit but lower than the test’s quantitation limit. In contrast, test results above the quantification limit don’t carry the J qualifier - they have lower uncertainty and are not considered to be estimates. The laboratory’s detailed reports that accompany this study give detection and quantification limits for each individual test result shown below.

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
<b>Infant cereal: rice</b>									
Beech-Nut	Rice Single Grain Baby Cereal - Stage 1, from about 4 months	Cereal - rice	117	86	3.5	5.4	0.582	Charlottesville, VA	Wegmans
BioKinetics	BioKinetics Brown Rice Organic Sprouted Whole Grain Baby Cereal	Cereal - rice	353	144	3.1 *	31.7	2.32	Washington, DC	amazon.com
Earth’s Best	Whole Grain Rice Cereal	Cereal - rice	138	113	22.5	14.7	2.41	San Diego, CA	99 Cents Only Stores
Earth’s Best	Whole Grain Rice Cereal	Cereal - rice	126	107	17.8	13.4	2.19	Portland, ME	Hannaford
Gerber	Rice Single Grain Cereal	Cereal - rice	106	74	3.9	11.1	1.79	Gambell, AK	ANICA Native Store
Healthy Times	Organic Brown Rice Cereal - 4+ months	Cereal - rice	153	133	67.4	12.1	1.53	Washington, DC	amazon.com
Kitchdee Organic	Baby Cereal Rice and Lentil - 6+ months	Cereal - rice	79.3	78	10.9	13.1	4.06	Washington, DC	amazon.com
<b>Infant cereal: multi- and single non-rice grain</b>									
Gerber	MultiGrain Cereal - Sitter 2nd Foods	Cereal - mixed and multi-grain	37	31	5.3	26.2	0.367 *	Detroit, MI	Meijer
HappyBABY	Oats & Quinoa Baby Cereal Organic Whole Grains with Iron - Sitting baby	Cereal - mixed and multi-grain	10.2	--	0.9 *	12.4	<0.14	Minneapolis, MN	Target
Beech-Nut	Oatmeal Whole Grain Baby Cereal - Stage 1, from about 4 months	Cereal - oatmeal	23.8	--	2.2	13	<0.139	Portland, OR	Fred Meyer
Earth’s Best	Whole Grain Oatmeal Cereal	Cereal - oatmeal	29.5	27	2 *	20.1	<0.277	Portland, ME	Hannaford
Gerber	Oatmeal Single Grain Cereal	Cereal - oatmeal	26.9	--	3 *	13	<0.281	Washington, DC	Safeway
HappyBABY	Oatmeal Baby Cereal, Clearly Crafted - Organic Whole Grains - for sitting baby	Cereal - oatmeal	6.3 *	--	<0.5	10	<0.14	Albany, NY	buybuyBABY
Harvest Hill	Instant Oatmeal, Maple & Brown Sugar	Cereal - oatmeal	13.5	--	8.1	5.8	<0.14	Houston, TX	Dollar Tree
Cream of Wheat	Cream of Wheat Instant Original Flavor	Cereal - other single-grain	19.5	--	21.8	36.7	<0.14	San Diego, CA	99 Cents Only Stores

## APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Gerber	Barley Single Grain Cereal- Supported Sitter 1st Foods	Cereal - other single-grain	10.6 *	--	3 *	13.7	< 0.279	Detroit, MI	Meijer
Gerber	Whole Wheat Whole Grain Cereal - Sitter 2nd Foods	Cereal - other single-grain	40.6	39	5.5	50.8	< 0.14	Cincinnati, OH	Kroger
NurturMe	Organic Quinoa Cereals - Quinoa + Sweet Potato + Raisin	Cereal - other single-grain	35.9	26	39.8	20.3	0.389 *	San Diego, CA	99 Cents Only Stores
<b>Infant formula</b>									
365 organic (Whole Foods)	Organic Milk Based Powder Infant Formula with Iron	Formula	4.1 *	--	2.7	0.7 *	< 0.139	Boulder, CO	Whole Foods Market
Baby's Only Organic	Organic Non-GMO Dairy Toddler Formula	Formula	3.8 *	--	1.6 *	< 0.5	< 0.139	Boulder, CO	Whole Foods Market
Earth's Best	Organic Sensitivity - DHR/ARA Infant Formula with Iron Organic Milk-Based Powder	Formula	< 4.4	--	1.6 *	1.4 *	< 0.278	Portland, ME	Hannaford
Enfamil	ProSobee Soy Infant Formula, Milk-Free Lactose-Free Powder with Iron	Formula	6.2 *	--	7.8	6.9	< 0.14	Columbia, SC	Publix
Enfamil	Infant - Infant Formula Milk-Based with Iron - 0-12 months	Formula	< 2.2	--	2	0.7 *	< 0.138	Charlottesville, VA	Wegmans
Gerber	Good Start Gentle HM-O and Probiotics Infant Formula with iron; Milk Based Powder - Stage 1, birth to 12 months	Formula	5.2 *	--	0.9 *	< 0.5	< 0.14	Cincinnati, OH	Kroger
HappyBABY	Organic Infant Formula with Iron, Milk Based Powder - 0-12 months	Formula	< 4.5	--	3.7	< 1.1	< 0.286	Washington, DC	amazon.com
Meijer	Meijer Baby, Infant Formula - Milk-Based Powder with Iron - Birth - 12 months	Formula	< 4.4	--	2.3 *	3.1 *	0.417 *	Detroit, MI	Meijer
Parent's Choice (Walmart)	Organic Infant With Iron Milk-Based Powder - Stage 1 through 12 months	Formula	3.2 *	--	3.9	0.7 *	< 0.134	Charlottesville, VA	Walmart
Plum Organics	Gentle Organic Infant Formula with Iron, Milk-Based Powder - 0-12 months <sup>†</sup>	Formula	4.6 *	--	4.7	< 1.1	< 0.278	Washington, DC	amazon.com
Similac	Similac Advance OptiGRO Powder - Milk-Based	Formula	4.6 *	--	2	< 0.5	< 0.139	Gambell, AK	ANICA Native Store
Simple Truth Organic (Kroger)	Infant Formula with Iron, Organic Milk-Based Powder	Formula	3.6 *	--	2.7	0.6 *	< 0.135	Portland, OR	Fred Meyer
up & up (Target)	Infant - Infant Formula with Iron, Milk-Based Powder, DHA and Dual Prebiotics	Formula	< 2.2	--	1.5 *	3.1	< 0.138	Minneapolis, MN	Target
<b>Vegetable - single, carrot</b>									
Beech-Nut	Classics Sweet Carrots - 2	Veggie - single - carrot	< 2.1	--	27.2	6.8	0.15 *	Washington, DC	Safeway
Beech-Nut	Classics Sweet Carrots - Stage 2	Veggie - single - carrot	< 2.2	--	23.5	8	0.212 *	Portland, ME	Hannaford
Beech-Nut	Organics Just Carrots - Stage 1	Veggie - single - carrot	2.8 *	--	1.3 *	1.4 *	0.142 *	Minneapolis, MN	Target



## APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Earth's Best	Carrots Organic Baby Food - 2, 6 months +	Veggie - single - carrot	4.1 *	--	1.1 *	< 0.5	0.224 *	Boulder, CO	Whole Foods Market
Earth's Best	Carrots Organic Baby Food 2 - 6 months+	Veggie - single - carrot	3.5 *	--	1.6 *	5.2	0.24 *	Columbia, SC	Publix
Earth's Best	First Carrots Organic Baby Food - 1, 4 months+	Veggie - single - carrot	5.2 *	--	1.6 *	4.4	0.222 *	Charlottesville, VA	Wegmans
Gerber	Diced Carrots Veggie Pick-Ups™	Veggie - single - carrot	< 2.2	--	11.8	27.7	0.223 *	Washington, DC	Safeway
Gerber	Carrot - Sitter 2nd food	Veggie - single - carrot	< 2.2	--	9.4	31.4	0.214 *	Minneapolis, MN	Target
Gerber	Carrot - Supported Sitter 1st Foods	Veggie - single - carrot	< 2.2	--	11	42.2	0.248 *	Columbia, SC	Publix
Meijer	True Goodness Organic Carrots Baby Food	Veggie - single - carrot	< 2.2	--	1.4 v	7.7	< 0.141	Detroit, MI	Meijer
O Organics (Albertson/Safeway)	Organic Carrots Baby Food - 2	Veggie - single - carrot	3.3 *	--	1.9	5.2	< 0.14	Washington, DC	Safeway
Parent's Choice (Walmart)	Carrot - Stage 2, 6+ months	Veggie - single - carrot	< 2	--	2.3	11.2	< 0.128	Charlottesville, VA	Walmart
<b>Vegetable - single, sweet potato</b>									
Beech-Nut	Naturals Just Sweet Potatoes - Stage 1, from about 4 months	Veggie - single - sweet potato	2.4 *	--	14.1	4	< 0.136	Albany, NY	buybuyBABY
Beech-Nut	Organics Just Sweet Potatoes - Stage 1, from about 4 months	Veggie - single - sweet potato	3.8 *	--	7.3	2.7	< 0.142	Cincinnati, OH	Kroger
Beech-Nut	Classics Sweet Potatoes - Stage 2, from about 6 months	Veggie - single - sweet potato	2.8 *	--	24.1	3.4	< 0.138	Portland, OR	Fred Meyer
Earth's Best	Sweet Potatoes Organic Baby Food - 1, 4 months +	Veggie - single - sweet potato	3.3 *	--	14.7	4.6	< 0.136	Boulder, CO	Whole Foods Market
Earth's Best	Sweet Potatoes Organic Baby Food 2 - from about 6 months	Veggie - single - sweet potato	3.1 *	--	12.9	3	< 0.136	Portland, OR	Fred Meyer
Earth's Best	Sweet Potatoes Organic Baby Food 2 - 6 months+	Veggie - single - sweet potato	4.3 *	--	6.9	1.6 *	< 0.138	Columbia, SC	Publix
Gerber	Sweet Potato Supported Sitter 1st Foods Tub	Veggie - single - sweet potato	2.4 *	--	20.3	4.7	< 0.139	Washington, DC	Safeway
Gerber	Sweet Potato - Sitter 2nd Food	Veggie - single - sweet potato	3.9 *	--	29.3	5.8	< 0.138	Minneapolis, MN	Target
Gerber	Sweet Potato - Supported Sitter 1st Foods	Veggie - single - sweet potato	6.9	--	14.6	3.5	< 0.138	Cincinnati, OH	Kroger
HappyBABY	Organics Sweet Potatoes - Stage 1	Veggie - single - sweet potato	5.8 *	--	1.5 *	1 *	< 0.142	Portland, ME	Hannaford

## APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
HappyBABY	Organics Sweet Potatoes - Stage 1	Veggie - single - sweet potato	6 *	--	2.2	0.8 *	< 0.14	Detroit, MI	Meijer
HappyBABY	Sweet Potatoes - Stage 1	Veggie - single - sweet potato	27.5	29**	2	1.6 *	< 0.141	Columbia, SC	Publix
Meijer	Meijer Baby Sweet Potatoes - 2nd Stage	Veggie - single - sweet potato	11.9	--	1.3 *	0.8 *	< 0.14	Portland, ME	Hannaford
Meijer	True Goodness Organic Sweet Potatoes Baby Food - Stage 2	Veggie - single - sweet potato	2.6 *	--	0.8 *	0.6 *	< 0.14	Detroit, MI	Meijer
Parent's Choice (Walmart)	Sweet Potato - Stage 1, 4-6 months	Veggie - single - sweet potato	4.3 *	--	4.3	1.4 *	< 0.141	Charlottesville, VA	Walmart
Plum Organics	Just Sweet Potato Organic Baby Food - 1, 4 months & up	Veggie - single - sweet potato	3.1 *	--	5.6	2.3	< 0.142	Boulder, CO	Whole Foods Market
Plum Organics	Just Sweet Potato Organic Baby Food - 1, 4 months & up	Veggie - single - sweet potato	2.3 *	--	14	2.7	< 0.14	Washington, DC	Safeway
<b>Vegetable - single (other than carrot, sweet potato)</b>									
Beech-Nut	Classics Sweet Peas - Stage 2	Veggie - single - other	6.3 *	--	1.1 *	1.6 *	< 0.138	Portland, ME	Hannaford
Beech-Nut	Beechnut Naturals Just Butternut Squash - Stage 1	Veggie - single - other	< 2.2	--	1.3 *	1.2 *	< 0.139	Detroit, MI	Meijer
Beech-Nut	Organic Just Pumpkin - Stage 1, from about 4 months	Veggie - single - other	2.6 *	--	4	1.1 *	< 0.139	Portland, OR	Fred Meyer
Earth's Best	Winter Squash Organic Baby Food - 2, 6 months +	Veggie - single - other	< 2.2	--	0.8 *	< 0.5	< 0.137	Cincinnati, OH	Kroger
Earth's Best	First Peas Organic Baby Food 1 - 4 months+	Veggie - single - other	5.9 *	--	3.8	< 0.5	< 0.14	Columbia, SC	Publix
Gerber	Pea - Sitter 2nd foods	Veggie - single - other	< 2.2	--	0.7 *	< 0.5	< 0.14	Gambell, AK	ANICA Native Store
Gerber	Green Bean - Sitter 2nd Food	Veggie - single - other	< 2.1	--	0.8 *	2.8	< 0.135	Minneapolis, MN	Target
Gerber	Green Bean - Supported Sitter 1st Foods	Veggie - single - other	< 2.2	--	0.7 *	0.6 *	< 0.142	Cincinnati, OH	Kroger
Parent's Choice (Walmart)	Organic Butternut Squash Vegetable Puree - Stage 2, 6+ months	Veggie - single - other	< 2.2	--	4.2	0.9 *	< 0.138	Charlottesville, VA	Walmart

## APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
<b>Fruit - single</b>									
Applesnax	Applesauce with Cinnamon	Fruit - single - apple	< 2.1	--	1.7	< 0.5	< 0.134	Dallas, TX	Dollar Tree
Beech-Nut	Organic Just Apples - Stage 1, from about 4 months	Fruit - single - apple	< 2	--	< 0.5	< 0.5	< 0.126	Charlottesville, VA	Wegmans
Earth's Best	Apples Organic Baby Food 2 - from about 6 months	Fruit - single - apple	6.5	--	1.5 *	< 0.5	< 0.141	Portland, OR	Fred Meyer
Mott's	Mott's Applesauce Apple	Fruit - single - apple	< 2.2	--	< 0.5	< 0.5	< 0.139	San Diego, CA	Family Dollar
Seneca	Cinnamon Apple Sauce	Fruit - single - apple	5.6 *	--	3.7	0.7 *	< 0.138	San Diego, CA	99 Cents Only Stores
Beech-Nut	Naturals Bananas - Stage 1, from about 4 months	Fruit - single - banana	< 2.1	--	< 0.5	< 0.5	< 0.136	Albany, NY	buybuyBABY
Gerber	Banana - Sitter 2nd Foods	Fruit - single - banana	< 2.1	--	< 0.5	< 0.5	< 0.135	Gambell, AK	ANICA Native Store
Meijer	Meijer Baby Bananas - 2nd Stage	Fruit - single - banana	< 2.2	--	< 0.5	< 0.5	< 0.138	Detroit, MI	Meijer
Gerber	Peach - Sitter 2nd Foods	Fruit - single - other	7.3	--	2.4	2.1	0.142 *	Gambell, AK	ANICA Native Store
Orchard Naturals	Mandarin Oranges in Light Syrup	Fruit - single - other	< 2.2	--	< 0.5	< 0.5	< 0.139	Houston, TX	Dollar Tree
Plum Organics	Just peaches - organic baby food - for 4+ months (stage 1)	Fruit - single - other	7.2	--	0.9 *	< 0.5	< 0.139	Albany, NY	buybuyBABY
Earth's Best	First pears - 1, 4 months+	Fruit - single - pear	4.3 *	--	1.2 *	1.5 *	< 0.135	Houston, TX	99 Cents Only Stores
Gerber	Pear - Sitter 2nd foods	Fruit - single - pear	4.2 *	--	1.1 *	2.5	0.169 *	Gambell, AK	ANICA Native Store
HappyBABY	Organic Pears - Stage 1	Fruit - single - pear	7.4	--	1 *	0.8 *	< 0.138	Boulder, CO	Whole Foods Market
HappyBABY	Clearly Crafted Prunes Organic Baby Food, 1, 4+ months	Fruit - single - prune	< 2.1	--	2	< 0.5	< 0.136	Charlottesville, VA	Wegmans
Sprout	Prunes Organic Baby Food - 1 starting solids	Fruit - single - prune	3.9 *	--	6.1	< 0.5	0.245 *	Albany, NY	buybuyBABY
<b>Fruit &amp; Veggie, Mixed</b>									
Beech-Nut	Naturals Beets, Pear & Pomegranate - 2	Fruit and veggie - mixed	< 2.2	--	0.9 *	4.7	< 0.139	Washington, DC	Safeway
Gerber	Organic Mango Apple Carrot Kale - Sitter 2nd foods	Fruit and veggie - mixed	3.3 *	--	1.1 *	11.4	0.212 *	Gambell, AK	ANICA Native Store
Gerber	Carrot Pear Blackberry - Sitter 2nd Foods	Fruit and veggie - mixed	2.7 *	--	3.6	18.2	< 0.141	Washington, DC	gerber.com
Gerber	Organic Apple Blueberry Spinach - Sitter 2nd Food	Fruit and veggie - mixed	5 *	--	1.5 *	1.8	< 0.141	Houston, TX	99 Cents Only Stores

## APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
HappyBABY	Simple Combos Apples, Spinach & Kale - 2	Fruit and veggie - mixed	3 *	--	4.3	4.9	0.182 *	Portland, ME	Hannaford
O Organics (Albertson/Safeway)	Organic Apple, Sweet Potato & Carrot Baby Food	Fruit and veggie - mixed	2.6 *	--	0.7 *	1.1 *	<0.142	Washington, DC	Safeway
Plum Organics	Just Prunes Organic Baby Food - 1, 4 months & up	Fruit and veggie - mixed	7.6	--	2.5	<0.5	0.194 *	Boulder, CO	Whole Foods Market
Sprout	Carrot Apple Mango Organic Baby Food - 2, 6 months & up	Fruit and veggie - mixed	6.1	--	2.1	15.1	<0.131	Charlottesville, VA	Wegmans
up & up (Target)	Apple and Carrot Baby Food, Fruit + Vegetable Blend, 6+ months	Fruit and veggie - mixed	<2.3	--	0.7 *	<0.6	<0.146	Minneapolis, MN	Target
Gerber	Apple Sweet Potato with Cinnamon - Toddler 12+ months	Fruit and veggie - mixed	<2.2	--	3.1	0.7 *	<0.139	Houston, TX	99 Cents Only Stores
Plum Organics	Pumpkin Banana Papaya Cardmom - 6 months and up	Fruit and veggie - mixed	2.4 *	--	1.4 *	2.4	<0.139	San Diego, CA	99 Cents Only Stores
Beech-Nut	Classics Mixed Vegetables - Stage 2	Veggie - mixed	<2.2	--	17.9	8.6	<0.139	Portland, ME	Hannaford
Earth's Best	Spinach and Potato Organic Baby Food - 2, 6+ months	Veggie - mixed	6.4	--	1.4 *	3	<0.13	Charlottesville, VA	Wegmans
Gerber	Carrot Sweet Potato Pea - Sitter 2nd Foods	Veggie - mixed	2.4 *	--	6.7	2.1	<0.137	Gambell, AK	ANICA Native Store
<b>Juice - 100% apple</b>									
365 organic (Whole Foods)	100% Juice - Apple from Concentrate	Juice - 100% fruit	2.5 *	--	0.7 *	<0.5	<0.13	Boulder, CO	Whole Foods Market
Gerber	Apple Juice from Concentrate - Toddler 12+ months	Juice - 100% fruit	3.1 *	--	2.1	<0.5	<0.137	Portland, ME	Hannaford
Juicy Juice	Juicy Juice 100% Juice - Apple	Juice - 100% fruit	3.6 *	--	1 *	<0.5	<0.14	Dallas, TX	Dollar Tree
Kidgets	Toddler Apple Juice from Concentrate	Juice - 100% fruit	<2.2	--	0.6 *	<0.5	<0.141	San Diego, CA	Family Dollar
<b>Juice - 100% fruit juice, non-apple or mixed</b>									
Apple & Eve	Elmo's Punch - 100% Juice Organics	Juice - 100% fruit	<2.1	--	<0.5	<0.5	<0.137	Boulder, CO	Whole Foods Market
Gerber	Apple Prune Juice from Concentrate - Toddler 12+ months	Juice - 100% fruit	5.6 *	--	3.3	<0.5	<0.136	Cincinnati, OH	Kroger
Gerber	Variety Pack Juices from Concentrate - White Grape	Juice - 100% fruit	9.9	--	11.1	<0.5	<0.135	Portland, OR	Fred Meyer
Gerber	Pear Juice from Concentrate 100% Juice - Toddler 12+ months	Juice - 100% fruit	4 *	--	1.1 *	0.9 *	<0.136	Charlottesville, VA	Wegmans
Juicy Juice	100% Juice Fruit Punch	Juice - 100% fruit	2.5 *	--	0.6 *	0.6 *	<0.139	San Diego, CA	Family Dollar
<b>Drinks - not 100% fruit juice</b>									
Good2Grow	Fortified Water - Orange Mango	Drink - not 100% fruit	<2.1	--	1.8	<0.5	<0.136	Dallas, TX	99 Cents Only Stores

## APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Orgain	Kids Protein Organic Nutrituional Shake Vanilla Flavor - Ages 1 to 13	Drink - not 100% fruit	3.9 *	--	0.6 *	< 0.5	< 0.14	Charlottesville, VA	Wegmans
Pediasure	Grow & Gain Chocolate Shake	Drink - not 100% fruit	3 *	--	1.3 *	2	< 0.136	Portland, ME	Hannaford
Repone	Suero/Electrolyte Solution with Zinc Fruit Flavor	Drink - not 100% fruit	< 2.2	--	< 0.5	< 0.5	< 0.139	San Diego, CA	Family Dollar
Yoo-hoo	Yoo-hoo Chocolate Drink	Drink - not 100% fruit	2.6 *	--	0.8 *	1.1 *	< 0.134	Houston, TX	Dollar Tree
<b>Meals, including fruits &amp; veggies with grains</b>									
Deluxe Pasta	Macaroni & cheese, Original Flavor	Meal	6.7	--	7	25	< 0.14	Houston, TX	Dollar Tree
Earth's Best	Chicken and Brown Rice Organic Baby Food - 2, 6+ months	Meal	34.4	13	18.3	1.9	0.232 *	Washington, DC	amazon.com
Earth's Best	Organic Turkey Quinoa Apple Sweet Potato Homestyle Meal Puree	Meal	< 2.2	--	1.9	1.9	< 0.139	Columbia, SC	Publix
Earth's Best	Organic Chicken Pot Pie Homestyle Meal Puree	Meal	< 2.2	--	1.2 *	2.1	< 0.139	Columbia, SC	Publix
Gerber	Mashed Potatoes & Gravy with Roasted Chicken and a Side of Carrots - Toddler	Meal	< 2.2	--	2.4	17.5	< 0.139	Portland, ME	Hannaford
Gerber	Chicken Rice Dinner - Sitter 2nd Foods	Meal	19.1	--	2.3 *	8.9	< 0.236	Washington, DC	gerber.com
Gerber	Turkey Rice Dinner - Sitter 2nd Foods	Meal	6.2 *	--	5.2	3.4	< 0.139	Washington, DC	gerber.com
Happy Tot	Love My Veggies Bowl - Cheese & Spinach Ravioli with Organic Marinara Sauce - for tots and tykes	Meal	4.8 *	--	8.5	19.6	0.148 *	Columbia, SC	Publix
Kraft	Macaroni & Cheese Dinner, Original Flavor	Meal	8.1	--	2	38.6	< 0.139	Houston, TX	Dollar Tree
Sprout	Garden Vegetables Brown Rice with Turkey - for 8 months & up, Stage 3	Meal	7.2	--	1.6 *	2.5	< 0.138	Albany, NY	buybuyBABY
Earth's Best	Organic Sweet Potato Cinnamon Flax & Oat - Wholesome Breakfast Puree - 2, for 6+ months	Fruit and veggie - with grain/meat/ dairy/legume	< 2.2	--	4.4	4.3	< 0.138	Albany, NY	buybuyBABY
HappyBABY	Apples, Sweet Potatoes & Granola Clearly Crafted Organic Baby Food - 2	Fruit and veggie - with grain/meat/ dairy/legume	3.6 *	--	5.2	1.5 *	< 0.142	Washington, DC	Safeway
Parent's Choice (Walmart)	Organic Strawberry Carrot and Quinoa Fruit & Veg Puree - Stage 2, 6+ months	Fruit and veggie - with grain/meat/ dairy/legume	2.5 *	--	3.6	1.8	< 0.125	Charlottesville, VA	Walmart
Plum Organics	Apple, Raisin & Quinoa Organic Baby Food - 2 <sup>†</sup>	Fruit and veggie - with grain/meat/ dairy/legume	5.6 *	--	2.2	1.9	0.145 *	Washington, DC	Safeway
Sprout	Butternut Chickpea Quinoa & Dates Organic Baby Food	Fruit and veggie - with grain/meat/ dairy/legume	2.3 *	--	0.8 *	< 0.5	< 0.137	Columbia, SC	Publix

## APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
<b>Meat</b>									
Beech-Nut	Classics Chicken & Chicken Broth - 1	Meat	< 2.2	--	< 0.5	< 0.5	< 0.137	Washington, DC	Safeway
Beech-Nut	Classics Turkey and Turkey Broth - Stage One	Meat	< 2	--	1 *	< 0.5	< 0.128	Charlottesville, VA	Wegmans
Gerber	Lil' Sticks Chicken Sticks - Toddler	Meat	< 2.2	--	3.5	2.3	< 0.138	Washington, DC	Safeway
Gerber	Beef and Gravy 2nd foods	Meat	< 2.1	--	2.1	< 0.5	0.251 *	Columbia, SC	Publix
Gerber	Ham and Gravy 2nd foods	Meat	< 2.2	--	1 *	< 0.5	< 0.141	Columbia, SC	Publix
O Organics (Albertson/Safeway)	Strained Organic Turkey and Turkey Gravy Baby Food - 2	Meat	2.7 *	--	1 *	< 0.5	< 0.137	Washington, DC	Safeway
<b>Snacks - Puffs</b>									
Comforts (Kroger)	Blueberry Little Puffs Cereal Snack	Snack - rice puffs	83.3	61	8.5	36.9	0.835	Cincinnati, OH	Kroger
Earth's Best	Sesame Street Organic Peanut Butter Baked Corn Puffs	Snack - puffs, non-rice	< 4.4	--	1.3 *	26	< 0.278	Washington, DC	amazon.com
HappyBABY	Superfood Puffs - Apple & Broccoli Organic Grain Snack - for crawling baby	Snack - rice puffs	266	83	8.2	11	2.16	Albany, NY	buybuyBABY
HappyBABY	Superfood Puffs Organic Grain Snack - Sweet Potato & Carrot	Snack - rice puffs	295	91	3.7	12.2	1.94	Washington, DC	amazon.com
Gerber	Puffs Banana Cereal Snack - Crawler 8+ months	Snack - rice puffs	44.5	--	9.2	16	0.376 *	Houston, TX	99 Cents Only Stores
O Organics (Albertson/Safeway)	Organic Puffs - Apple Strawberry	Snack - rice puffs	309	133	7.5	15.2	3.29	Washington, DC	Safeway
Simple Truth Organic (Kroger)	Whole Grain Puffs Broccoli & Spinach	Snack - rice puffs	307	126	9.8	13.5	3.68	Cincinnati, OH	Kroger
Sprout	Organic Quinoa Puffs Baby Cereal Snack - Apple Kale	Snack - puffs, contains rice	107	47	39.3	41.5	1.31	Washington, DC	amazon.com
<b>Snacks - Teething biscuits &amp; rice rusks/cakes</b>									
Baby Mum-Mum	Banana Rice Rusks	Snack - teething biscuits & rice rusks/cakes	104	53	5.2	2.3	1.72	Cincinnati, OH	Kroger
HappyBABY	Organic Rice Cakes Puffed Rice Snack - Apple	Snack - teething biscuits & rice rusks/cakes	455	47	1.7	5.4	3.18	Boulder, CO	Whole Foods Market
Meijer	Apple Rice Rusks Baked Rice Snack	Snack - teething biscuits & rice rusks/cakes	50.2	--	3.2 *	3.9	1.99	Detroit, MI	Meijer
Parent's Choice (Walmart)	Organic Strawberry Rice Rusks - Stage 2, 6+ months	Snack - teething biscuits & rice rusks/cakes	108	66	26.9	2.4	2.05	Charlottesville, VA	Walmart
Simple Truth Organic (Kroger)	Mini Rice Cakes Apple - 7+ months	Snack - teething biscuits & rice rusks/cakes	65.9	--	8.7	0.8 *	1.1	Cincinnati, OH	Kroger

## APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
Cué tara	Animalitos Galleta Crackers (Animal Crackers)***	Snack - teething biscuits & rice rusks/cakes	4.1 *	--	6.4	25.5	< 0.139	San Diego, CA	99 Cents Only Stores
Gerber	Teether Wheels - Apple Harvest - Crawlers	Snack - teething biscuits & rice rusks/cakes	51.5	--	2.1 *	3.8	0.588 *	Washington, DC	Safeway
HappyBABY	Organic Teethers Blueberry & Purple Carrot - Sitting baby	Snack - teething biscuits & rice rusks/cakes	67	--	6	8.2	2.26	Charlottesville, VA	Wegmans
Lil' Dutch Maid	Saltine Crackers***	Snack - teething biscuits & rice rusks/cakes	10.1	--	1.5 *	19.1	< 0.138	San Diego, CA	99 Cents Only Stores
Meijer	True Goodness Organic Teethers Baked Rice Snack - Vegetable	Snack - teething biscuits & rice rusks/cakes	65	36	3.9	6.7	2.41	Detroit, MI	Meijer
Nosh!	Baby Munchables Organic Teething Wafers - Banana & Mango	Snack - teething biscuits & rice rusks/cakes	110	62	6.6	3.1 *	3.44	Detroit, MI	Meijer
Plum Organics	Little Teethers Organic Multigrain Teething Wafers - Banana with Pumpkin - Baby Crawler	Snack - teething biscuits & rice rusks/cakes	49.9	--	1.4 *	6.3	0.726	Columbia, SC	Publix
<b>Snacks - Other (yogurt, biscuits, bars)</b>									
Beech-Nut	Breakfast On-the-Go Yogurt, Banana & Mixed Berry Blend - Stage 4 from about 12 months	Snack - other	< 2.2	--	0.7 *	< 0.5	< 0.139	Charlottesville, VA	Wegmans
Earth's Best	Sesame Street Organic Fruit Yogurt Smoothie - Apple Blueberry	Snack - other	4.4 *	--	2.5	< 0.5	< 0.135	Portland, OR	Fred Meyer
Earth's Best	Sunny Days Snack Bars - Sweet Potato Carrot	Snack - other	13.9	--	3.8	10.5	0.161 *	Boulder, CO	Whole Foods Market
Ella's Kitchen	Organic Nibbly Fingers - Apples and Strawberries, 1+	Snack - other	27	--	3	7.8	0.216 *	Boulder, CO	Whole Foods Market
Gerber	Yogurt Blends Strawberry Snack - Crawler 8+ months	Snack - other	< 2.1	--	1 *	< 0.5	< 0.135	Gambell, AK	ANICA Native Store
Gerber	Fruit & Veggie Melts - Truly Tropical Blend - Freeze-Dried Fruit & Vegetable Snack - Crawler, 8+ months	Snack - other	22.6	--	12.2	26.8	0.455	Albany, NY	buybuyBABY
Gerber	Arrowroot Biscuits - Crawler 10+ months	Snack - other	13.1	--	12.5	25.9	< 0.279	Washington, DC	walmart.com
Little Duck Organics	100% Pressed Fruit Snacks + Probiotics - Pomegranate, Blueberry & Acai	Snack - other	13.6	--	15	1 *	< 0.138	Albany, NY	buybuyBABY
Nostalgia	Marias Cookies Galletas	Snack - other	3.8 *	--	6.6	22	0.14 *	San Diego, CA	99 Cents Only Stores
Parent's Choice (Walmart)	Little Hearts Strawberry Yogurt Cereal Snack - Stage 3, 9+ months	Snack - other	56.1	--	5.2	26.1	0.941	Charlottesville, VA	Walmart
Plum Organics	Mighty Morning Bar - Blueberry Lemon - Tots: 15 months & up	Snack - other	40 *	39	3.4	24.3	< 0.137	Cincinnati, OH	Kroger



## APPENDIX A: Laboratory Test Results for Heavy Metals (continued)

Brand	Food	Food type	Arsenic (total, ppb)	Arsenic (inorganic, ppb)	Lead (ppb)	Cadmium (ppb)	Mercury (total, ppb)	Metro area where purchased	Retailer
SOBISK	Breakfast Biscuits - Golden Oats	Snack - other	9	--	60.1	9.6	0.143 *	Dallas, TX	Dollar Tree
Sprout	Organic Crispy Chews Red Fruit Beet & Berry with Crispy Brown Rice Toddler Fruit Snack	Snack - other	19.2	--	7.7	1.2 *	0.185 *	Charlottesville, VA	Wegmans
<b>Supplement</b>									
Gerber	Soothe Probiotic Colic Drops	Supplement	4.4 *	--	< 0.5	< 0.5	< 0.139	Washington, DC	walmart.com

## Notes

The symbol "<" indicates no detection, with a test result less than the indicated limit of detection.

The symbol "\*\*" indicates test results that are estimated, between the limit of detection and the limit of quantitation.

The symbol "--" indicates that no test was performed.

\*\* Total arsenic value is higher than inorganic arsenic value but falls within the allowable and expected analytical error. For example, this ratio of inorganic to total arsenic of 105% falls within the FDA method for arsenic speciation in rice, which allows this ratio to range from 65 – 135%.

\*\*\* This food was purchased from a dollar store and is not marketed specifically as a baby food. Because dollar stores carry so few standard baby foods, this food is purchased by parents as an alternative, according to information from HBBF's local partner participating in this study.

† Food is no longer manufactured.

‡ This value is the average of 3 tests of total arsenic (44, 37, and 39 ppb). The original homogenized bar was tested twice, and homogenate of a second, separate bar from the same box was tested once..

## APPENDIX B: RECENT SCIENCE ON THE IMPACT OF HEAVY METALS TO CHILDREN'S BRAIN DEVELOPMENT

The table below details 23 recent studies on the impact of arsenic, cadmium, lead and mercury on the development of children's brains. Evidence in the scientific literature spans decades; the studies below are a sampling of publications over the past seven years.

Study number	Study	What did the study find?
<b>Metals combinations: Recent studies of children's exposures to toxic-metal combinations and impacts to the developing brain</b>		
1	Grandjean and Landrigan 2014	In this update to their 2006 systematic review, the authors added six chemicals to their earlier review of the science on the toxicity to the developing brain and nervous system of lead, methylmercury, polychlorinated biphenyls, arsenic, and toluene. The authors provide an estimate of 24 million IQ points lost from combined exposures to lead and mercury.
2	Freire 2018	In a study of the cognitive development of 302 Spanish 4 and 5 year old children, researchers found lower scores on pre-school neurodevelopmental tests among children who had been exposed to higher levels of arsenic and mercury during pregnancy, as measured in the placenta at birth. The study also found a synergistic effect between arsenic and lead indicated by lower general cognitive scores.
3	Kim 2018	A study of 140 Korean 1- and 2-year-olds and their mothers compared the chemicals in pregnant women's blood or urine, or in breast milk after delivery, with standard pre-school tests of neurodevelopmental performance. The mothers' blood lead levels were inversely associated with psychomotor development in their children. Pregnant women with higher levels of a combination of heavy metals in their blood also had children with more behavior problems.
4	Pan 2018	Researchers tested the blood and urine of 530 children ages 9-11 living near an industrialized area and 264 from another town in the same city in South China as a reference. A significant decrease in IQ scores was identified in children from the industrialized town, who had statistically higher geometric mean concentrations of lead, cadmium, and mercury. Blood lead had a significant negative association by itself, and the additive impact of all four metals raised concerns.
5	Lucchini 2019	Scientists studied the effect of co-exposures to socio-economic stressors and arsenic, cadmium, lead, mercury and other metals in schoolchildren in Taranto, Italy. Biomonitoring and an analysis of the distance between the residence of 299 children ages 6 to 12 and point sources of industrial emissions were done along with tests of children's cognitive functions. The researchers found that metal levels in the children's blood and urine had a negative cognitive impact. Lead exposure was shown to have a neurocognitive effect even at very low levels of blood lead concentration for children of low socio-economic status.
<b>Arsenic: Recent studies of children's exposures to arsenic and impacts to the developing brain</b>		
6	Rodríguez-Barranco 2013	This meta-analysis details 13 articles reporting "a significant negative effect on neurodevelopment and behavioural disorders" from arsenic exposure during pregnancy and early childhood.
7	Wasserman 2014	Columbia University researchers report on their assessment of 272 third to fifth graders in Maine who lived in homes with well water. The study found an average loss of 5-6 IQ points among those who drank well water contaminated with arsenic at or above 5 parts per billion. This level is common in some parts of the U.S. and is lower than the legal limit in public water supplies (10 parts per billion).
8	Tsuji 2015	This 2015 literature review identifies 24 studies linking low-level arsenic exposure to neurological harm in children.
9	Signes-Pastor 2019	This study focused on the impact of arsenic exposure from food. The urine of 400 4- and 5-year-olds was tested for arsenic. The children took tests that measure neuropsychological development. Children with higher arsenic levels performed worse on tests of motor function. Boys showed diminished working memory with higher arsenic exposures.
<b>Cadmium: Recent studies of children's exposures to cadmium and impacts to the developing brain</b>		
10	Sanders 2015	This review of recent scientific literature found 16 studies on cadmium's neurotoxic impacts to children. In these studies, lower IQ scores and more learning disorders and special education needs were correlated to higher cadmium levels in children.
11	Gustin 2018	A study of 1500 mother and child pairs in Bangladesh associated prenatal and childhood cadmium exposure with lower intelligence in boys. In girls, there were indications of altered behavior for both prenatal and childhood exposure.
12	Lee 2018	A study of 76 children with ADHD and 46 control children found cadmium levels negatively correlated with Full Scale Intelligence Quotient.
13	Al Osman 2019	This scientific review references studies that link children's cadmium exposure to IQ loss and other health endpoints, including kidney disease, osteoporosis, cardiovascular disease, stunted growth, and pediatric cancer.

## APPENDIX B: Recent Science on the Impact of Heavy Metals on Children's Brain Development (continued)

Study number	Study	What did the study find?
<b>Lead: Recent studies of children's exposures to lead and impacts to the developing brain</b>		
14	NTP 2012	The National Institutes of Health's National Toxicology Program evaluation of the toxicity of low-level lead exposure concludes that such exposures are responsible for intellectual deficits, diminished academic abilities, attention deficits, and problem behaviors, including impulsivity, aggression, and hyperactivity in children.
15	Zhang 2013	An analysis of the blood lead tests recorded before the age of 6 and the standardized test scores in grades 3, 5 and 8 of 21,281 students in the Detroit Public Schools found that early childhood lead exposure was negatively associated with academic achievement in elementary and junior high school.
16	Evens 2015	The study compared Chicago's birth registry, the blood lead registry and the scores on 3rd grade iSAT tests for 58,650 children. After adjusting for poverty, race/ethnicity, gender, maternal education and very low birth weight or preterm birth, the study concluded "Early childhood lead exposure is associated with poorer achievement on standardized reading and math tests in the third grade, even at very low blood lead levels."
17	Liu 2014	A study of 1341 children in the Jiangsu province of China compared blood lead at ages 3 to 5 with behavioral problems at age 6 and found a significant association. The authors report that the risk of clinical-level behavioral problems increased with blood lead concentration.
18	Lewis 2018	This study's 278 study participants were drawn from a large longitudinal study in Cleveland, Ohio that is examining the developmental effects of prenatal cocaine exposure. The children's blood was tested for lead at age 4, and their language skills were assessed at 4, 6, 10 and 12 years of age. The researchers found that lead exposure harmed both receptive and expressive language skills. Prenatal drug exposure was not related to the effects of lead on language skills.
19	Donzelli 2019	A systematic review of studies on the relationship between lead exposure and the diagnosis of ADHD identified 17 studies reporting an association between lead and ADHD.
<b>Mercury: Recent studies of children's exposures to mercury and impacts to the developing brain</b>		
20	Karagas 2012	A review of the literature on the health effects of low-level exposure to methylmercury concentrated on studies that include measurement of this toxic chemical in blood and hair of pregnant women and their children. The consistent finding in the researchers' review of the science on neurocognitive and behavior outcomes was the connection between prenatal mercury levels and psychomotor function, memory, verbal skills cognition in 7- to 14-year-old children.
21	Jacobson 2015	A 2015 study in Environmental Health Perspectives compared the IQs of 282 school-age children with the levels of mercury in umbilical cord blood taken at birth. The researchers found that prenatal mercury levels were associated with lower scores on school-age IQ tests.
22	Ryu 2017	A study of 458 mother child pairs in Korea found that blood mercury levels during late pregnancy and early childhood were associated with more autistic behaviors in children at 5 years of age, as assessed using the Social Responsiveness Scale.
23	Bellinger 2019	To derive an estimate of the global burden of intellectual disability from prenatal exposure to mercury, scientists conducted a meta-analysis of the available science and determined a dose-effect relationship of IQ reductions to increases in maternal hair mercury levels.

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## APPENDIX C: LABORATORY ANALYSIS – SUMMARY OF METHODS FOR HEAVY METALS TESTING

### BACKGROUND

HBBF commissioned a national laboratory recognized for its expertise in heavy metals analysis, Brooks Applied Labs (BAL) near Seattle Washington (<http://brooksupplied.com/>), to test 168 containers of baby food for total recoverable arsenic, lead, cadmium, and mercury; and speciated arsenic for a subset of samples.

BAL is accredited through the National Environmental Accreditation Program (NELAC), the Department of Defense (DOD), and the International Organization for Standardization (ISO). It has also earned state accreditations for a variety of metals analyses, including arsenic and mercury. It uses the most current microwave digestion and ICP-MS technologies, and specializes in heavy metals testing (including arsenic, lead, cadmium, and mercury). BAL's clients include local governments, industry, the federal government, and engineering consulting firms.

BAL specializes in low-level metal analysis, including analysis in food. It has tested a wide range of baby foods. Its sensitive methods can detect heavy metals in a wide range of baby food types, including grains, dairy, fruits and vegetables, and meat.

For the heavy metals analyses used in this study, BAL is accredited according to the ISO 17025 standard. BAL's methods are comparable to FDA methods (FDA 2012,2015), with two notable differences: 1) The extraction acid used by BAL gives optimum results specifically for the food type being analyzed, according to tests of a range of acids and other solvents; and 2) BAL achieves a lower limit of quantification (LOQ) for the analysis of inorganic arsenic than FDA. Other major analytical techniques are comparable: for example, both BAL and FDA rely on chromatography methods to separate arsenic species, and ICP-MS methods to detect heavy metals.

### SAMPLE PREPARATION

**Baby food receipt and storage:** BAL received 168 baby food containers in April and May 2019. BAL logged in samples for the analysis of total recoverable arsenic [As], cadmium [Cd], lead [Pb], and mercury [Hg].

BAL received and stored all samples according to BAL Standard Operating Procedures (SOPs) and EPA methodology. Samples were stored at ambient temperature, maintaining the shipping temperature of the samples. Once containers were opened and aliquots obtained for testing, samples were frozen.

**Sample homogenization:** Any foods which were heterogeneous (e.g., snack bars) were thoroughly homogenized prior to sample digestion. All equipment used for the homogenization process was pre-cleaned beforehand and subject to routine testing to ensure the accuracy of sample data.

**Sample digestion:** BAL prepared samples by the addition of hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) and concentrated nitric acid (HNO<sub>3</sub>) to a microwave digestion vessel, via method AOAC 2015.01, modified. BAL digested samples at a precise pressure and temperature in a controlled microwave digestion program.

### TOTAL METALS ANALYSIS BY AOAC 2015.01, MOD.

BAL developed method AOAC 2015.01, Mod (Heavy Metals in Food: Inductively Coupled Plasma-Mass Spectrometry) for analysis of total recoverable metals. The method was accepted as a First Action Method by the consensus standards developing organization AOAC, placing it in AOAC's process leading to formal method adoption.

BAL analyzed total recoverable As, Cd, and Pb according to this method, using inductively coupled plasma triple

quadrupole mass spectrometry (ICP-QQQ-MS). The ICPQQQ-MS method uses advanced interference removal techniques to ensure accuracy of the sample results. This technology allows for the removal of polyatomic and doubly-charged ions that can interfere with an isotope. This is a critical step for arsenic analysis, since arsenic is a monoisotopic element. For more information, visit the Interference Reduction Technology section on BAL's website, [brooksupplied.com](http://brooksupplied.com).

### TOTAL MERCURY ANALYSIS BY EPA METHOD 1631

BAL prepared samples for Hg analysis using the AOAC 2015.01, modified method, as described above. BAL analyzed sample preparations with stannous chloride (SnCl<sub>2</sub>) reduction, single gold amalgamation, and cold vapor atomic fluorescence spectroscopy (CVAFS) detection using a Brooks Rand Instruments MERX-T CVAFS Mercury Automated-Analyzer. The laboratory then blank corrected the Hg results as described in the relevant BAL SOP and evaluated results using adjusted reporting limits to account for sample aliquot size.

### ARSENIC SPECIATION ANALYSIS

**Sample digestion:** BAL digested baby food samples for arsenic speciation using a solution of trifluoroacetic acid (TFA). The TFA digestion method typically induces conversion of As(V) to As(III) in the samples and matrix spikes and induces conversion of As(III) to As(V) in the blank spikes. (This is also a characteristic of FDA's method.) Therefore, the accurate measurement resulting from this method is total inorganic arsenic (the sum of As(V) and As(III)), rather than results from individual valence states.

**Analysis of arsenic speciation:** Extracts from digestion were analyzed for total inorganic arsenic [InorgAs] (sum of As(III) and As(V)), monomethylarsonic acid [MMAs], and

dimethylarsinic acid [DMAs] using ion chromatography inductively coupled plasma collision reaction cell mass spectrometry (IC-ICP-CRC-MS). This method uses chromatography to separate the different arsenic species and ICP-CRC-MS to detect the arsenic. The CRC is an interference reduction technology to remove polyatomic ions that can interfere with arsenic.

## QA/QC AND CERTIFICATION

**Quality Assurance and Quality Control:** All analyses were conducted in accordance with BAL's Standard Operating Procedures. Each preparation batch also included four method blanks (BLKs), a laboratory fortified blank (BS), a certified reference material (SRM), a laboratory duplicate (DUP), and a matrix spike/matrix spike duplicate (MS/MSD) set. Post-preparation spikes (PS) were also included in the arsenic speciation batches. The sample results were reviewed and evaluated in relation to the QA/QC samples worked up at the same time. The BS recoveries, SRM recoveries, PS recoveries, and method blanks were evaluated against method criteria to ensure data quality.

**BAL certification:** BAL is ISO certified for elemental analyses (including arsenic, lead, cadmium, and mercury) and arsenic speciation analysis in food.

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## APPENDIX D: LABORATORY TEST RESULTS FOR PERCHLORATE

Results for analysis of perchlorate in a limited number of baby foods are listed below. Testing was commissioned by HBBF and performed by Southwest Research Institute, San Antonio, TX. The detailed laboratory report (SWRI 2019) is provided under “Resources” in HBBF’s online version of this heavy metals study, at [healthybabyfood.org](https://healthybabyfood.org).

Twenty-five foods were tested for perchlorate, with containers purchased from supermarkets near Washington DC and from online retailers. These 25 foods were also included in the heavy metals testing described in this report, but perchlorate testing was performed using food samples extracted from a separate container. The table below also lists the number of heavy metals detected in each of these foods, from Appendix A, to provide information on the full range of neurotoxic contaminants covered in this study and detected in the foods chosen for testing. This limited perchlorate testing is intended to spur further testing and research on perchlorate in baby food. It is not necessarily representative of perchlorate levels across the baby food market, but instead provides a snapshot of levels in containers of these 25 foods.

The qualifier “<” indicates that the perchlorate concentration was below the method detection limit, while “(\*)” indicates that the arsenic concentration was near the method detection limit and was estimated.

Brand	Food	Food type	Perchlorate (ppb)	Number of heavy metals detected in this food**
Healthy Times	Organic Brown Rice Cereal - 4+ months	Cereal - rice	7.1	4
Gerber	Rice Single Grain Cereal	Cereal - rice	4.6	4
BioKinetics	BioKinetics Brown Rice Organic Sprouted Whole Grain Baby Cereal	Cereal - rice	< 3.2	4
Beech-Nut	Rice Single Grain Baby Cereal - Stage 1, from about 4 months	Cereal - rice	< 3.2	4
Earth’s Best	Whole Grain Rice Cereal	Cereal - rice	< 3.2	4
Gerber	Oatmeal Single Grain Cereal	Cereal - oatmeal	7.7	3
Beech-Nut	Oatmeal Whole Grain Baby Cereal - Stage 1, from about 4 months	Cereal - oatmeal	4.2	3
Earth’s Best	Whole Grain Oatmeal Cereal	Cereal - oatmeal	2.7 *	3
HappyBABY	Oatmeal Baby Cereal, Clearly Crafted - Organic Whole Grains - for sitting baby	Cereal - oatmeal	1.6 *	2
Gerber	MultiGrain Cereal - Sitter 2nd Foods	Cereal - mixed and multi-grain	8.7	4
HappyBABY	Oats & Quinoa Baby Cereal Organic Whole Grains with Iron - Sitting baby	Cereal - mixed and multi-grain	2.4 *	3
Gerber	Whole Wheat Whole Grain Cereal - Sitter 2nd Foods	Cereal - other single-grain	4.2	3
NurturMe	Organic Quinoa Cereals - Quinoa + Sweet Potato + Raisin	Cereal - other single-grain	3.5	4
Gerber	Barley Single Grain Cereal- Supported Sitter 1st Foods	Cereal - other single-grain	3.3	3
Similac	Similac Advance OptiGRO Powder - Milk-Based	Formula	11.4	2
Earth’s Best	Organic Sensitivity - DHR/ARA Infant Formula with Iron Organic Milk-Based Powder	Formula	1.5 *	2
Enfamil	ProSobee Soy Infant Formula, Milk-Free Lactose-Free Powder with Iron	Formula	< 3.2	3
Earth’s Best	Spinach and Potato Organic Baby Food - 2, 6+ months	Veggie - mixed	19.8	3
Beech-Nut	Organics Just Carrots - Stage 1	Veggie - single - carrot	2.3	4
Parent’s Choice (Walmart)	Carrot - Stage 2, 6+ months	Veggie - single - carrot	0.64 *	2
HappyBABY	Simple Combos Apples, Spinach & Kale - 2	Fruit and vegetable - mixed	3.7	4



## APPENDIX D: Laboratory Test Results for Perchlorate (continued)

Brand	Food	Food type	Perchlorate (ppb)	Number of heavy metals detected in this food**
Plum Organics	Mighty Morning Bar - Blueberry Lemon - Tots: 15 months & up	Snack - bar	1.8 (J)	3
HappyBABY	Superfood Puffs - Apple & Broccoli Organic Grain Snack - for crawling baby	Snack - puffs	< 3.2	4
Baby Mum-Mum	Banana Rice Rusks	Snack - rice rusks and rice cakes	4.6	4
HappyBABY	Organic Rice Cakes Puffed Rice Snack - Apple	Snack - rice rusks and rice cakes	< 3.2	4

## Notes

The symbol "<" indicates no detection, with a test result less than the indicated limit of detection.

The symbol "\*\*" indicates test results that are estimated, between the limit of detection and the limit of quantification.

\*\* Heavy metal test data can be found in Appendix A. Perchlorate and metals tests used food from separate containers for each food, not a single container.

## REFERENCES

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## APPENDIX E: RESULTS OF IQ ANALYSIS: 15 FOODS ACCOUNT FOR OVER HALF OF TOTAL IQ LOSS FROM CHILDREN'S EXPOSURES TO ARSENIC AND LEAD IN BABY FOOD

Healthy Babies Bright Futures (HBBF) commissioned a new study from Abt Associates (Abt) to quantify the health impacts posed by multiple heavy metals in baby food. This work gives first-ever estimates of the population-wide decline in IQ from children's exposures to lead and arsenic in food, from birth to 24 months of age. It also gives the 15 baby foods that collectively account for 55 percent of the total IQ loss from these exposures.

### DATA USED IN IQ LOSS ANALYSIS

The analysis relies on two data sources published by the federal government:

**Foods babies eat:** What We Eat in America (WWEIA) data – 24-hour food recall data collected as part of The National Health and Nutrition Examination Survey (NHANES) – contains dietary intake measurements for the U.S. population, including babies. Dietary data are collected for up to two days for each respondent, including food type and quantity consumed. NHANES is run by the CDC's National Center for Health Statistics (NCHS) and was designed to collect information on the health and nutritional status of the U.S. civilian, non-institutionalized population through in-home interviews and physical examinations. Abt used this data to represent babies' daily food intake in this analysis.

**Arsenic and lead levels in baby food:** FDA's Total Diet Study (TDS), an ongoing FDA program, collects information on levels of various contaminants, including arsenic and lead, that occur in food and beverages commonly consumed by the U.S. population. FDA buys these foods as a consumer would, prepares them as directed, and then

analyzes the prepared foods for levels of the contaminants of interest. This process yields nationally representative estimates of contaminant levels in approximately 280 kinds of food and beverages. Abt used TDS arsenic and lead data to represent contaminant levels in the foods babies eat.

### ESTIMATING CHILDREN'S INTAKE OF ARSENIC AND LEAD

Steps and assumptions in estimating children's arsenic and lead intake include:

**Mapping the food intake and concentration datasets:** A mapping file<sup>1</sup> pairs TDS foods with similar foods included in the WWEIA dataset. The mapping file covers 2014-2016 TDS data cycles; Abt used all three of these years of data to represent the lead and arsenic levels in foods children eat. For WWEIA, FDA's mapping file covers 2003-2014. Abt used a subset of those years, WWEIA data cycles from 2009-2014, to represent the foods children eat. The earlier years of WWEIA data covered in FDA's mapping file (2003-2008) were considered less representative of children's current eating habits than the more recent data, and were therefore excluded from the analysis.

**Method used to account for arsenic and lead levels below detection limits:** Abt performed the Xue et al. (2010) method for summarizing values of TDS data that fall below the limit of detection (LOD), assigning half the LOD to values below the LOD if there was at least one detection among the many samples taken of each particular food; otherwise a value of 0 was assigned.

**Estimating children's intake of lead and arsenic:** Abt matched mean values for each TDS food with each food consumed in the WWEIA dataset according to the mapping file. The intake of arsenic and lead for each food consumed was calculated as the product of the concentration of each metal and the mass of each food consumed during the survey's period of record.

**Criteria for inclusion of surveyed children:** Abt included in the analysis all children with two days of dietary data from WWEIA, and used the mean lead/arsenic consumption value between the two days to represent each child's average daily lead/arsenic intake.

### ESTIMATING INORGANIC ARSENIC CONCENTRATIONS

FDA tests TDS foods for total arsenic, as opposed to inorganic arsenic. Inorganic arsenic is the form considered in studies of arsenic exposure and IQ loss, and for which concentration-response functions have been developed. Studies indicate that inorganic arsenic is more toxic than other forms (Abt 2017). Therefore, it was necessary to scale the total arsenic consumed by children to represent the portion that was inorganic. In the absence of more specific information, Abt assumed that 70 percent of total arsenic consumed in food was comprised of inorganic arsenic, as was done by the European Food Safety Authority in their 2014 report entitled "Dietary exposure to inorganic arsenic in the European population" (EFSA 2014). In certain cases, exceptions to the application of this rule were made using information about the arsenic makeup of particular foods as specified in Cubadda et al. (2017).

<sup>1</sup> provided by FDA to Abt (via personal correspondence)

Using this information, Abt assumed:

- 95% of total arsenic is inorganic in beverages, and 100% of total arsenic is inorganic in bottled water.
- 80% of total arsenic is inorganic in fruit.
- 60% of total arsenic is inorganic in rice.
- 95% of total arsenic is inorganic in wheat.
- 5% of total arsenic is inorganic in fish and shellfish, including New England clam chowder and tuna casserole.
- 90% of total arsenic is inorganic in vegetables.

In addition, Abt assumed the following inorganic arsenic compositions based on independent testing from data provided by HBBF, from laboratory results presented in HBBF (2017):

- 61% of total arsenic is inorganic in infant rice cereal.
- 53% of total arsenic is inorganic in infant multi-grain and non-rice cereals.

Abt also assumed the following inorganic arsenic compositions based on testing performed by FDA, from analysis of data from FDA (2014) provided by EDF (2018):

- 73% of total arsenic is inorganic in grape juice.
- 59% of total arsenic is inorganic in oat ring cereal.
- 56% of total arsenic is inorganic in teething biscuits.

All other foods not specifically mentioned were assumed to have 70% of total arsenic as inorganic arsenic, per EFSA (2014).

### ESTIMATING IQ LOSS FROM LEAD

Abt used the following steps to estimate IQ loss from lead intake:

1. Calculated baseline concurrent childhood lead uptake for each year of age from 0 to 7. Other sources of lead were accounted for by using U.S. Environmental Protection Agency's (EPA's) default levels for air, drinking water, and soil/dust lead exposure, as outlined in the agency's User's Guide for the Integrated Exposure Uptake Biokinetic model for Lead in Children (IEUBK), excluding the contribution from food (EPA 2007). These estimates were input into approximation equations from EPA's IEUBK model that were derived by Zartarian et al. (2017) to convert this baseline lead uptake to blood lead level (without food intake).

2. Estimated the lead consumption from WWEIA's contribution to the child's blood lead level by converting lead consumption to lead uptake (assuming 50% lead uptake from dietary ingestion), and the same estimation equations of EPA's IEUBK model described in Step 1 to convert the baseline lead uptake estimated above plus the additional lead uptake from food to blood lead level (with food intake).

3. Assumed each child's daily lead intake from food was equal to their survey-specific lead intake for the entire year of their age in the WWEIA data, and equal to the population-wide mean lead intake from food for every other year of life.. For example, the estimated mean lead intake for a child when they were one year old (assuming they are not one year old in the WWEIA data) is represented by calculating the mean lead intake of all one-year-olds in the dataset.

4. Calculated lifetime blood lead without food by taking the average of the baseline concurrent blood lead levels for each year of life as estimated by the Zartarian et al. (2017) IEUBK estimation equations (in Step 1). Calculated lifetime blood lead with food by taking the average of the mean value of blood leads with both other sources of lead and food in the data (from step 2) for each year of life, except

for the year of each child's age in the WWEIA data, which is represented by their personal blood lead level with the added contribution from food (as described above).

5. Used the Crump et al. (2013) concentration-response function to estimate the lifetime IQ loss due to the difference in lifetime blood lead level based on the contribution of lead in food using the following equation:

$$IQ\ Loss = \beta \times \ln\left(\frac{PbB_1 + 1}{PbB_2 + 1}\right)$$

where:

Beta = -3.25

$PbB_1$  = Baseline lifetime blood lead level without food

$PbB_2$  = Baseline lifetime blood lead level including food contribution

### ESTIMATING IQ LOSS FROM INORGANIC ARSENIC

Abt used the following steps to estimate IQ loss as a result of inorganic arsenic intake:

1. Assumed each child's inorganic arsenic intake was equal to their personal inorganic arsenic intake for the entire of their current age, and equal to the population-wide mean inorganic arsenic intake for every other year of life specific to that year of life and the study population. For example, the mean inorganic arsenic intake for a child when they were one year old (assuming they are not one year old in the WWEIA data) is represented by calculating the mean inorganic arsenic intake of all one-year-olds in the dataset.

2. Calculated lifetime inorganic arsenic consumption from food by taking the average of the mean inorganic arsenic consumption figures from the dataset for each year of life, except for the year of each child's age in the WWEIA data, which is represented by their personal mean daily inorganic arsenic intake (as described above).

3. Used a concentration-response function based on a study by Wasserman et al. (2004), as described in Abt 2017, to estimate lifetime IQ loss based on arsenic drinking water concentration:

$$IQ\ Loss = \beta \times \Delta AsDW$$

where:

Beta = 0.44

$\Delta AsDW$  = Change in arsenic drinking water concentration

4. Converted lifetime inorganic arsenic consumption from food (from Step 2) to an approximate drinking water concentration by assuming that each child in the Wasserman et al. (2004) consumes 1 Liter of water per day, as was done by CalEPA when deriving a chronic Reference Exposure Level for inorganic arsenic consumption in 2008 (CalEPA, 2008). This was necessary to match the concentration-response function in Step 3.

Because the Wasserman et al. (2004) concentration-response function for IQ loss is linear, the approximate equivalent drinking water concentration calculated in Step 4 represents the change in arsenic drinking water concentration used in the equation in Step 3. In other words, the IQ loss for a population with any background level of arsenic exposure using the Wasserman et al. (2004) function will always be equal to the change in arsenic concentration from the calculation in Step 4 multiplied by the beta. This differs from the lead analysis, where the background exposure from other sources matters due to the log transformation of lead in the concentration-response function.

### ESTIMATING TOTAL LIFETIME IQ LOSS FROM LEAD AND ARSENIC IN FOODS BABIES EAT

Total IQ loss from food was estimated as the sum of the lifetime IQ loss due to lead consumption from food with the lifetime IQ loss due to inorganic arsenic consumption from food.

### DEFINING THE CONTRIBUTION OF EACH FOOD TO IQ LOSS

Total IQ loss was estimated for each food from the TDS based on lead consumption alone, arsenic consumption alone, and lead consumption and arsenic consumption combined. It was necessary to calculate the lifetime IQ loss for each instance that a food was consumed individually, since the method for calculating lead uptake is specific to age. Thus, an instance of food consumption of the same food in the same amount could be responsible for two different magnitudes of IQ loss due to lead if the two children who consumed the food were of different ages.

Lifetime IQ loss from lead was calculated for each instance of food consumption using the IQ Loss equation as above. However, PbB2 was assumed equal to baseline lifetime blood lead level plus the additional blood lead from the consumption of that one food for the current year of their life. All other years of blood lead averaged into the lifetime blood lead equation for PbB2 are assumed equal to the baseline. Each of these incremental IQ losses due to each instance of a particular food being consumed were multiplied by their respective survey weight, and summed to estimate the total IQ loss attributable to each food across the population of children.

Lifetime IQ loss from arsenic was calculated using the concentration response function above for each food consumption instance, but was then multiplied by the survey weight, and summed to estimate the total IQ loss attributable to each food across the population of children.

These two IQ losses for each food were then added together to estimate the total IQ loss from each food due to both lead and arsenic combined.

### ESTIMATING POPULATION-WIDE TOTAL LIFETIME IQ LOSS DUE TO LEAD, ARSENIC, AND LEAD AND ARSENIC COMBINED

Total IQ loss due to lead, arsenic, and lead and arsenic combined were calculated by multiplying each child's estimated lifetime IQ loss from each of these sources by the corresponding survey weight, and summed together for all children aged zero to less than two in the survey data.

### LIMITATIONS

A baseline level of inorganic arsenic could not be estimated; it was necessary for us to use a linear concentration-response function relating inorganic arsenic to IQ loss. Thus, Abt was unable to provide a range of results related to the many concentration response functions presented in Abt's previous arsenic analysis (Abt 2017). There is a great deal of uncertainty in the inorganic arsenic dose conversions, and it should be noted that Abt is assuming that the linear extrapolation holds for different population and lower doses compared to the original studies. Estimates of IQ loss from lead in food are considered to be lower-bound estimates, from Abt's experience applying a range of accepted concentration-response functions from other studies. HBBF recommends that future work to estimate IQ loss from heavy metals in food include a full range of accepted functions, for a more comprehensive view of potential health impacts for children.

**INTERPRETATION OF RESULTS: LIFETIME CONSUMPTION AND IQ LOSS**

Results are presented in Abt (2019b) for children under the age of two. The results reflect lifetime consumption / IQ loss, and are focused on the group of children in the WWEIA data who are ages 0 to 2 at the time of the survey.

**RESULTS OF THE ANALYSIS**

Results are detailed in Abt 2019b. Abt estimates more than 11 million IQ points lost among children ages 0-24 months from exposure to arsenic and lead in food. The table below shows the top 15 foods contributing to IQ loss for those children, from an analysis of all WWEIA foods that are matched to TDS foods.

Food consumed by child age 0 - 24 months	Percent of total harm (fraction of total IQ points lost for children under 2, from lead and arsenic in food)	Primary toxic metal of concern	Of these foods: Rank for potency (considering average IQ points lost per child eating the food; 1=highest, 15=lowest)	Food name from FDA's Total Diet Study (TDS) - source of As/Pb concentration data	Food name(s) from What We Eat in America survey (WWEIA)*, source of data on food types and amounts that children eat
Rice dishes, including with beans & veggies	10.0%	Arsenic	1	Fried rice, meatless, from Chinese carry-out	SPANISH RICE; RICE W/ BEANS; FLAVORED RICE&PASTA MIXTURE (INCL RICE-A-RONI); and other rice dishes
Milk, whole	8.4%	Arsenic	7	Milk, whole, fluid	MILK, COW'S, FLUID, WHOLE
Rice, white and brown	7.0%	Arsenic	6	Rice, white, enriched, cooked	Rice, white, cooked, fat not added in cooking; Rice, white, cooked, fat added in cooking, made with oil; RICE, WHITE, COOKED, REGULAR, NO FAT ADD IN COOKING
Apple juice	6.1%	Arsenic	10	Apple juice, bottled; BF, juice, apple	APPLE JUICE; APPLE JUICE, BABY
Infant formula	5.3%	Lead	4	BF, Infant formula, milk-based, iron fortified RTF	ENFAMIL LIPIL, W/ IRON, INFANT FORMULA, PREP FROM PDR; SIMILAC ADVANCE, W/ IRON, INFANT FORMULA, PREP FROM PDR; Similac Advance, infant formula, prepared from powder, made with baby water; and other infant formulas
Fruit juice blend (100% juice)	4.1%	Arsenic	8	Fruit juice blend (100% juice), canned/bottled	FRUIT JUICE BLEND, 100% JUICE
Infant rice cereal	2.7%	Arsenic	3	BF, cereal, rice, dry, prepared w/ water	RICE CEREAL, BABY, DRY, INSTANT
Grape juice	2.0%	Lead and arsenic	5	Grape juice, frozen conc, reconstituted; BF, juice, grape	GRAPE JUICE
Cheerios and other oat ring cereals	1.6%	Arsenic	12	Oat ring cereal	CHEERIOS; HONEY NUT CHEERIOS
Sweet potato (baby food)	1.6%	Lead and arsenic	2	BF, sweet potatoes	SWEETPOTATOES, BABY, STRAINED; SWEETPOTATOES, BABY, JUNIOR
Soft cereal bars and oatmeal cookies	1.4%	Arsenic	11	Granola bar, w/ raisins	Kellogg's Nutri-Grain Cereal Bar; COOKIE, OATMEAL; COOKIE, OATMEAL, W/ RAISINS OR DATES

Food consumed by child age 0 - 24 months	Percent of total harm (fraction of total IQ points lost for children under 2, from lead and arsenic in food)	Primary toxic metal of concern	Of these foods: Rank for potency (considering average IQ points lost per child eating the food; 1=highest, 15=lowest)	Food name from FDA's Total Diet Study (TDS) - source of As/Pb concentration data	Food name(s) from What We Eat in America survey (WWEIA)*, source of data on food types and amounts that children eat
Macaroni and cheese	1.4%	Lead and arsenic	13	Macaroni and cheese, prepared from box mix	Macaroni or noodles with cheese, made from packaged mix; MACARONI OR NOODLES W/ CHEESE; MACARONI/NOODLES W/ CHEESE, MADE FROM DRY MIX
Puffs and teething biscuits	1.3%	Lead and arsenic	9	BF, teething biscuits	GERBER FINGER FOODS, PUFFS, BABY FOOD; Cookie, teething, baby; Cookie, fruit, baby food; Finger Foods, Puffs, baby food
Bottled drinking water	1.2%	Arsenic	15	Bottled drinking water (mineral/spring), not carbonated or flavored	WATER, BOTTLED, UNSWEETENED; Water, baby, bottled, unsweetened
Fruit yogurt	1.2%	Lead	14	Yogurt, lowfat, fruit-flavored	YOGURT, FRUIT VARIETY, WHOLE MILK; YOGURT, FRUIT VARIETY, LOWFAT MILK

## Notes

\* What We Eat in America (WWEIA) dataset: Many foods are matched to a single TDS food in Abt's calculation method (per FDA's mapping file). Foods shown above are those most commonly consumed by children 0-24 mo, from among the WWEIA foods matched to each listed TDS food.

Results shown above for IQ loss and potency ranking correspond to children from 0-24 months old

BF = baby food, in TDS food names

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**ADDENDUM - REVISIONS TO FDA'S MAPPING FILE**

In calculations described above, Abt assumed the following matches that differed from the FDA's original mapping file, to provide more representative concentration estimates where inexact FDA matches yielded inappropriate estimates. In these cases, high arsenic levels in clam chowder from the TDS dataset were inconsistent with arsenic levels typical for the matched foods from WWEIA listed below.

**TDS food from FDA mapping file:** Clam chowder, New England, canned, cond, prepared w/ whole milk

- **WWEIA matched foods:** CHICKEN NOODLE SOUP, CREAM OF; CHICKEN SOUP, CREAM OF, PREPARED W/ WATER; CHICKEN/TURKEY SOUP, CM OF, CAN, RED SOD, W/ MILK; CHICKEN SOUP, CREAM OF, NS AS TO MILK OR WATER
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Soup, chicken noodle, canned, cond, prepared w/ water; and TDS food #2: Milk, whole, fluid
  
- **WWEIA matched foods:** POTATO SOUP, CREAM OF, W/ MILK; POTATO SOUP, NS AS TO MADE W/MILK OR WATER; POTATO & CHEESE SOUP
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Potato, boiled (w/out peel); and TDS food #2: Milk, whole, fluid
  
- **WWEIA matched food:** CORN SOUP, CREAM OF, PREPARED W/ WATER
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Corn, fresh/frozen, boiled); and TDS food #2: Milk, whole, fluid
  
- **WWEIA matched foods:** MUSHROOM SOUP, CREAM OF, PREP W/ MILK; MUSHROOM SOUP, CREAM OF, PREPARED W/ WATER; MUSHROOM SOUP, NFS
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Mushrooms, raw; and TDS food #2: Milk, whole, fluid
  
- **WWEIA matched food:** CHEDDAR CHEESE SOUP
- **Revised TDS food:** Assume 50/50 mixture of these 2 TDS foods: TDS food #1: Cheese, cheddar, natural (sharp/ mild); TDS food #2: Milk, whole, fluid
  
- **WWEIA matched food:** WHITE SAUCE, MILK SAUCE
- **Revised TDS food:** Milk, whole, fluid



## APPENDIX F: DATA AND CALCULATIONS—AVERAGE HEAVY METALS LEVELS FOR HIGHER-RISK FOODS AND SAFER ALTERNATIVES

The table below summarizes test results from HBBF and FDA for foods highlighted in this report's charts on higher-risk baby foods and safer alternatives. The tables are the basis of the finding in our study that the safer food choices we list contain 80 percent less arsenic, lead and other toxic heavy metals, on average, than the higher-risk foods. That number is calculated as the average reduction for the 5 food categories shown on the Executive Summary chart entitled "What Parents Can Do." The foods shown on that chart, and the average total heavy metals levels that are the basis of that calculation, are indicated in the table below.

Study	Food	Number of samples	Metal concentration, parts per billion (ppb)						Source of inorganic arsenic level, and average ratio of inorganic to total arsenic		This food's data is shown in safer-choices food charts in this study	Reference for ratio of inorganic to total arsenic
			Lead	Cadmium	Mercury	Arsenic, total	Arsenic, inorganic	Total metals	Measured - ratio of inorganic to total arsenic is shown below	Calculated - Assumed ratio of inorganic to total arsenic is shown below		
Infant rice cereal (dry, white and brown rice)												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Infant rice cereal (dry, white and brown rice)	7	18.44	14.50	2.13	153.19	105.00	140.07	0.77			HBBF 2019 Baby Food study
HBBF 2017 Arsenic in Infant Cereal Study (HBBF 2017)	Infant rice cereal (dry, white and brown rice)	42					85.00		0.61		X	HBBF 2017
FDA testing, 2013 and 2014 (FDA 2016, Abt 2017)	Infant rice cereal (dry, white and brown rice)	76					103.00					
Other cereals (dry)												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Other cereals (non-rice)	11	8.35	20.18	0.14	23.07	12.23	40.91		0.53		HBBF 2017
HBBF 2017 Arsenic in Infant Cereal Study (HBBF 2017)	Other cereals (non-rice)	63					14.00		0.53		X	HBBF 2017
Infant rice cereal (dry, prepared)												
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, cereal, rice, dry, prepared with water	14	0.50	3.10	0.17	26.60	16.83	20.60		0.63	X	HBBF 2017 and this study (see Note 6)
Other cereals (dry, prepared)												
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, cereal, oatmeal, dry, prepared with water	14	0.00	3.20	0.00	3.60	1.91	5.11		0.53		HBBF 2017
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, cereal, mixed, dry, prepared with water	14	0.88	7.30	0.00	6.50	3.45	11.63		0.53		HBBF 2017
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, cereal, oatmeal with fruit, prepared with water	14	0.00	3.30	0.00	4.00	2.12	5.42		0.53		HBBF 2017
FDA's Total Diet Study 2014-2017 (FDA 2019)	Average of the 3 TDS Other Cereals above	14	0.29	4.60	0.00	4.70	2.49	7.38			X	

## APPENDIX F: Data and Calculations—Average Heavy Metals Levels for Higher-Risk Foods and Safer Alternatives (continued)

Study	Food	Number of samples	Metal concentration, parts per billion (ppb)						Source of inorganic arsenic level, and average ratio of inorganic to total arsenic		This food's data is shown in safer-choices food charts in this study	Reference for ratio of inorganic to total arsenic
			Lead	Cadmium	Mercury	Arsenic, total	Arsenic, inorganic	Total metals	Measured - ratio of inorganic to total arsenic is shown below	Calculated - Assumed ratio of inorganic to total arsenic is shown below		
Carrot, baby food												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Carrots, baby food	12	7.84	12.62	0.17	2.20	1.98	22.62		0.90		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, carrots	14	8.70	19.00	0.00	1.50	1.35	29.05		0.90		Cubadda 2016
HBBF and FDA studies listed above	Sample-weighted average	26	8.51	17.58	0.04	1.66	1.49	27.62			X	
Sweet potato, baby food												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Sweet potato, baby food	17	10.35	2.62	0.07	5.67	5.10	18.14		0.90		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, sweet	14	13.70	3.60	0.00	1.90	1.71	19.01		0.90		Cubadda 2016
HBBF and FDA studies listed above	Sample-weighted average	31	12.73	3.32	0.02	2.99	2.69	18.76			X	
Other fruits and vegetables, baby food												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Other fruits and vegetables, baby food (excludes carrots and sweet potatoes)	39	2.27	2.41	0.09	3.13	2.66	7.42		0.85	X	Cubadda 2016 (see Note 7)
Fruit juice												
HBBF 2019 Baby Food Study (see Appendix A of this document)		9	2.31	0.36	0.07	3.71	0.83	3.56		0.95		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, juice, apple	14	0.25	0.00	0.00	3.30	3.14	3.39				
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, juice, grape	14	2.70	0.00	0.00	13.60	12.92	15.62				
FDA's Total Diet Study 2014-2017 (FDA 2019)	BF, juice, pear	14	1.30	0.75	0.00	4.70	4.47	6.52				
HBBF and FDA studies listed above	Sample-weighted average	51	1.48	0.26	0.00	6.97	6.44	8.18			X	
Alternative to fruit juice - Tap water												
HBBF's Lead in Water Testing Program (HBBF 2019)	Tap water	743	2.00	0.09	NT	0.50	0.50	2.59		1.00	X	Cubadda 2016 (see Note 8)
Puffs (rice)												
HBBF 2019 Baby Food Study (see Appendix A of this document)		7	12.31	20.90	1.94	201.69	81.00	116.16	0.44			EDF 2018 and HBBF 2019 Baby Food Study (see Note 9)
FDA testing, 2013 and 2014 (EDF 2018)		31	19.10	19.30	0.00	119.00	54.90	93.30	0.58			EDF 2018 (see Note 10)
HBBF and FDA studies listed above	Sample-weighted average	38	17.85	19.59	0.36	134.23	59.71	97.51			X	

## APPENDIX F: Data and Calculations—Average Heavy Metals Levels for Higher-Risk Foods and Safer Alternatives (continued)

Study	Food	Number of samples	Metal concentration, parts per billion (ppb)						Source of inorganic arsenic level, and average ratio of inorganic to total arsenic		This food's data is shown in safer-choices food charts in this study	Reference for ratio of inorganic to total arsenic
			Lead	Cadmium	Mercury	Arsenic, total	Arsenic, inorganic	Total metals	Measured - ratio of inorganic to total arsenic is shown below	Calculated - Assumed ratio of inorganic to total arsenic is shown below		
Teething biscuits (rice) and rice rusks												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Teething biscuits and rice rusks	10	6.57	4.29	1.95	68.68	41.80	54.61	0.47			EDF 2018 and HBBF 2019 Baby Food Study (see Note 11)
FDA testing, 2013 and 2014 (EDF 2018)	Teething biscuits and rice rusks	27	12.00	9.20	0.00	84.80	46.40	67.60	0.54			EDF 2018 (see Note 12)
HBBF and FDA studies listed above	Sample-weighted average		10.53	7.87	0.53	80.44	45.16	64.09			X	
Alternatives to teething biscuits												
FDA's Total Diet Study 2014-2017 (FDA 2019)	Banana, raw	14	0.00	0.00	0.00	0.00	0.00	0.00				
FDA's Total Diet Study 2014-2017 (FDA 2019)	Cucumber, peeled, raw	14	0.00	1.23	0.00	11.95	10.76	11.99		0.90		Cubadda 2016
FDA studies listed above	Sample-weighted average	28	0.00	0.62	0.00	5.98	5.38	5.99			X	
Non-rice snacks and teethers												
HBBF 2019 Baby Food Study (see Appendix A of this document)	Non-rice snacks and teethers (biscuits, cookies, teethers)	10	8.90	14.20	0.20	15.30	10.71	34.01		0.70		EFSA 2014
Other snacks recommended as alternatives to rice-based snacks												
FDA's Total Diet Study 2014-2017 (FDA 2019)	Apple (red), raw (with peel)	14	0.53	0.00	0.00	2.10	1.68	2.21		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Applesauce: Applesauce, bottled	14	0.00	0.00	0.00	0.59	0.47	0.47		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Bananas	14	0.00	0.00	0.00	0.00	0.00	0.00		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Barley with diced veggies: No data available											
FDA's Total Diet Study 2014-2017 (FDA 2019)	Beans: White beans, dry, boiled	14	0.00	2.60	0.00	0.97	0.68	3.28		0.70		EFSA 2014
FDA's Total Diet Study 2014-2017 (FDA 2019)	Cheese: Cheese, cheddar, natural (sharp/mild)	14	0.59	0.22	0.00	0.00	0.00	0.81		0.70		EFSA 2014
FDA's Total Diet Study 2014-2017 (FDA 2019)	Grapes: Grapes (red/green), raw	14	2.94	0.47	0.00	3.99	3.19	6.60		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Hard-boiled egg	14	0.00	0.00	0.00	0.72	0.50	0.50		0.70		EFSA 2014
FDA's Total Diet Study 2014-2017 (FDA 2019)	Peaches: Peach, raw/frozen	14	0.00	0.54	0.00	4.39	3.51	4.05		0.80		Cubadda 2016
FDA's Total Diet Study 2014-2017 (FDA 2019)	Yogurt: Yogurt, lowfat, fruit-flavored	14	2.65	0.00	0.00	0.00	0.00	2.65		0.70		EFSA 2014

APPENDIX F: Data and Calculations—Average Heavy Metals Levels for Higher-Risk Foods and Safer Alternatives (continued)

Study	Food	Number of samples	Metal concentration, parts per billion (ppb)						Source of inorganic arsenic level, and average ratio of inorganic to total arsenic		This food's data is shown in safer-choices food charts in this study	Reference for ratio of inorganic to total arsenic
			Lead	Cadmium	Mercury	Arsenic, total	Arsenic, inorganic	Total metals	Measured - ratio of inorganic to total arsenic is shown below	Calculated - Assumed ratio of inorganic to total arsenic is shown below		
FDA's Total Diet Study 2014-2017 (FDA 2019)	Average for the snacks listed above	126	0.75	0.43	0.00	1.42	0.00	1.17				
FDA's Total Diet Study 2014-2017 (FDA 2019) and HBBF 2019 Baby Food Study	Average for snacks listed above and the non-rice snacks from this study		1.49	1.68	0.02	2.68	1.89	5.07			X	

Notes			
<p>* Sample-weighted averages account for the 3 individual samples that comprise each TDS composite sample.</p> <p>1. NT = not tested</p> <p>2. "HBBF 2019 Baby Food Study" refers to this study; individual sample data are shown in Appendix A.</p> <p>3. Zero is shown for metals levels from FDA's Total Diet Study for results that fall below the limit of quantitation. For mercury, a zero may also indicate that the test was not conducted.</p> <p>4. Average inorganic arsenic is calculated from average total arsenic value in cases where HBBF lacked access to data for individual samples.</p> <p>5. Calculations of average levels for FDA TDS data are calculated using the Xue (2010) method for treatment of results below the quantitation limit.</p> <p>6. Ratio of inorganic to total arsenic is the sample-weighted average of data from HBBF 2017 and this study.</p> <p>7. From Cubadda 2017: Inorganic arsenic is 90% total for vegetables, 80% total for fruit. 85% is used here.</p> <p>8. Metals levels shown are averages from HBBF tap water testing from over 700 homes in 43 states.</p> <p>9. Inorganic arsenic for one puffs sample was not measured, and was instead calculated from the change FDA 2013-14 study ratio (EDF 2018).</p> <p>10. Averages are derived from sample data available at EDF 2018.</p> <p>11. Inorganic arsenic for 4 samples were not measured, and were instead calculated from the FDA 2013-14 study ratio (EDF 2018).</p> <p>12. Averages are derived from sample data available at EDF 2018.</p>			

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Healthy Babies Bright Futures (HBBF) is an alliance of scientists, nonprofit organizations and donors working to create and support initiatives that measurably reduce exposures to neurotoxic chemicals in the first thousand days of development.

Our efforts are inspired and supported by science and data, and designed to help restore the chance for a full life to children who would otherwise face brain-diminishing exposures to toxic chemicals beginning in utero.

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